# Canada Vigilance
# Summary of Reported Adverse Reactions

## Search Criteria

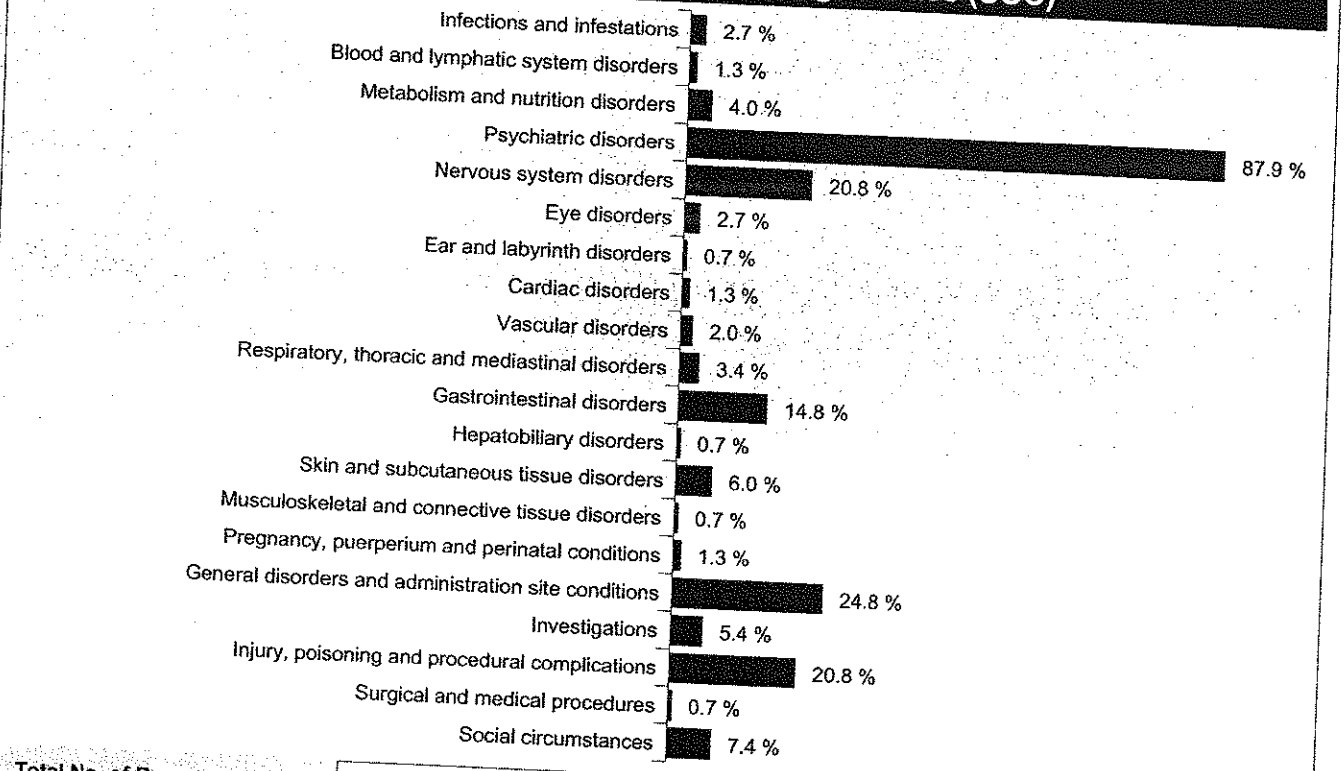
| | |
|---|---|
| **Report Runtime:** | 2014-08-07 - 2:51:42 PM |
| **Range for Initial Receive Date:** | 2012-04-13 to 2014-06-30 |
| **Active Ingredient:** | cannabis sativa |
| **Product Role:** | Suspect |
| **Dosage Form:** | -All- |
| **Route of Administration:** | -All- |
| **Range for Age (years):** | -All- |
| **Patient Gender:** | -All- |
| **Case Serious?** | -All- |
| **Case Outcome:** | -All- |
| **Report Source:** | -All- |
| **Reporter Type:** | -All- |
| **Country of Occurrence:** | Domestic |
| | |
| **AER(s) have at least one Preferred Term related (multi-axial concept) to the following:** | |
| **System Organ Class:** | 'Any' System Organ Class |
| **High Level Group Term:** | This filtering criteria was not applied. |
| **High Level Term:** | This filtering criteria was not applied. |
| | |

CAVEAT: This summary is based on information from adverse event reports submitted by health professionals and laypersons either directly to Health Canada or via market authorization holders. Each report represents the suspicion, opinion or observation of the individual reporter. The Canada Vigilance Program is a spontaneous reporting system that is suitable to detect signals of potential health product safety issues during the post-market period. The data has been collected primarily by a spontaneous surveillance system in which adverse reactions to health products are reported on a voluntary basis. Under reporting of adverse reactions is seen with both voluntary and mandatory spontaneous surveillance systems. Accumulated case reports should not be used as a basis for determining the incidence of a reaction or estimating risk for a particular product as neither the total number of reactions occurring, nor the number of patients exposed to the health product is known. Because of the multiple factors that influence reporting, quantitative comparisons of health product safety cannot be made from the data. Some of these factors include the length of time a drug is marketed, the market share, size and sophistication of the sales force, publicity about an adverse reaction and regulatory actions. In some cases, the reported clinical data is incomplete and there is not certainty that these health products caused the reported reactions. A given reaction may be due to an underlying disease process or to another coincidental factor. This information is provided with the understanding that the data will be appropriately referenced and used in conjunction with this caveat statement. (10/2007)

Report Runtime: 2014-08-07 - 2:51:42 PM
Health Product: See Search Criteria
Initial date of receipt: 2012-04-13 to 2014-06-30
Total Number of Reports: 149 Reports

# Canada Vigilance
## Summary of Reported Adverse Reactions

### Occurrences by Primary System Organ Class (SOC)




Total No. of Reports: (Denominator) 149

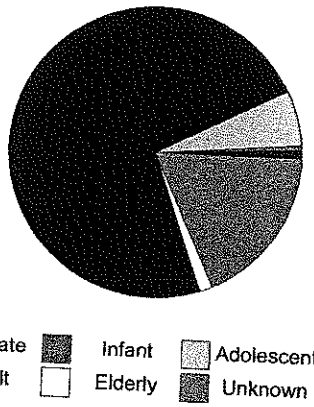
Number of reports (percentage) with one or more reaction terms in the SOC(s) above

MedDRA V17.0

### Age Group

| | | |
|---|---|---|
| Neonate | 1 | 0.7 % |
| Infant | 1 | 0.7 % |
| Adolescent | 9 | 6.0 % |
| Adult | 109 | 73.2 % |
| Elderly | 2 | 1.3 % |
| Unknown | 27 | 18.1 % |

### Age Group




### Reason for Seriousness

| | |
|---|---|
| Death | 12 |
| LifeThreatening | 3 |
| Hospitalization Required | 13 |
| Disability | 1 |
| Congenital Anomaly | 0 |
| Other Medically Imp Condition | 119 |

### Patient Sex

| | | |
|---|---|---|
| Female | 39 | 26.2 % |
| Male | 106 | 71.1 % |
| Not Reported | 1 | 0.7 % |
| Not specified | 1 | 0.7 % |
| Unknown | 2 | 1.3 % |

### Serious Reports

| | |
|---|---|
| Yes | 137 |
| No | 12 |

The Definition for age groups has been taken from the International Conference on Harmonization (ICH) and have been defined as follows:

- Neonate - greater than zero and up to 27 days, inclusively
- Infant - greater than 27 days and less than 2 years
- Child - greater or equal to 2 and less than 12 years
- Adolescent - greater or equal to 12 and less than 19 years
- Adult - greater or equal to 19 and less than 65 years
- Elderly - greater or equal to 65 years

## Duplicate

### Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000449798 | 0 | 2012-07-11 | 2012-07-11 | MAH | CAN20120003166 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000450846 |
| Duplicate | 000505287 |
| Duplicate | 000505304 |
| Duplicate | 000555892 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| EFFEXOR XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Sexually inappropriate behaviour | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000450846 | 0 | 2012-07-17 | 2012-07-17 | MAH | 2012168927 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000449798 |
| Duplicate | 000505287 |
| Duplicate | 000505304 |
| Duplicate | 000555892 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| EFFEXOR XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Sexually inappropriate behaviour | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505287 | 0 | 2013-03-01 | 2013-03-01 | MAH | PHHY2013CA015761 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000449798 |
| Duplicate | 000450846 |
| Duplicate | 000505304 |
| Duplicate | 000555892 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| EFFEXOR XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE | Suspect | NOT SPECIFIED | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Sexually inappropriate behaviour | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505304 | 0 | 2013-03-01 | 2013-03-01 | MAH | PHHY2013CA015300 | Spontaneous | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000449798 |
| Duplicate | 000450846 |
| Duplicate | 000505287 |
| Duplicate | 000555892 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| EFFEXOR XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE | Suspect | NOT SPECIFIED | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Sexually inappropriate behaviour | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000531636 | 0 | 2013-06-05 | 2013-06-05 | MAH | CAN20130004220 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | E2B_00089594 |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Unknown | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHADONE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |
| VALIUM 5 TAB | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000555892 | 0 | 2013-09-19 | 2013-09-19 | MAH | 2013268351 | Spontaneous | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000449798 |
| Duplicate | 000450846 |
| Duplicate | 000505287 |
| Duplicate | 000505304 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| EFFEXOR XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Sexually inappropriate behaviour | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000568885 | 0 | 2013-11-14 | 2013-11-14 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000573888 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 45 Years | Male | 69 Inches | 150 Pounds | Recovering/resolving |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE BERRY | Suspect | POWDER | Unknown | 41.7 Gram | 2 every 1 Day(s) | |
| VEGA ONE CHOCOLATE | Suspect | POWDER | Unknown | 41.7 Gram | 2 every 1 Day(s) | |
| VEGA ONE FRENCH VANILLA | Suspect | POWDER | Unknown | 41.7 Gram | 2 every 1 Day(s) | |
| VEGA ONE VANILLA CHAI | Suspect | POWDER | Unknown | 41.7 Gram | 2 every 1 Day(s) | |
| VEGA SPORT PERFORMANCE PROTEIN | Suspect | POWDER | Unknown | 36 | 1 every 1 Day(s) | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Appetite disorder | MedDRA V17.0 | |
| Bone marrow oedema | MedDRA V17.0 | |
| Chest pain | MedDRA V17.0 | |
| Dizziness | MedDRA V17.0 | |
| Nausea | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000573888 | 0 | 2013-11-26 | 2013-11-26 | MAH | CASE2013-05 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000568885 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| No | N/A | N/A | N/A |
| | Life Threatening: N/A | Hospitalization: N/A | Other Medically Imp Condition: N/A |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 45 Years | Male | 180 Centimetres | 68 Kilograms | Not recovered/not resolved |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Oral | 1 Dosage forms | 1 every 1 Day(s) | |
| VEGA SPORT PERFORMANCE PROTEIN | Suspect | POWDER | Oral | 1 Dosage forms | 1 every 1 Day(s) | |
| BONE STRENGTH TAKE CARE | Concomitant | TABLET | | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Bone marrow oedema | MedDRA V17.0 | |
| Gastrooesophageal reflux disease | MedDRA V17.0 | |
| Meniscus injury | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| E2B_00089594 | 0 | 2014-04-30 | 2014-04-30 | MAH | 1389675 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Duplicate | 000531636 |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | | Unknown | | | |
| DIAZEPAM | Suspect | TABLET | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHADONE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Linked

### Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000497065 | 0 | 2013-01-25 | 2013-01-25 | MAH | RB491032013 | Spontaneous | Physician | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Linked | 000497106 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| Neonate | Male | | 2.57 Kilograms | Recovered/resolved |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| NICOTINE | Suspect | NOT SPECIFIED | Unknown | 12 Units | every Day(s) | |
| OPIOID (S) | Suspect | NOT SPECIFIED | Unknown | | | |
| SUBUTEX | Suspect | TABLET | Transplacental | 16 Milligram | 1 every 1 Day(s) | 87 Day(s) |
| CIPRALEX | Concomitant | TABLET | | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug withdrawal syndrome neonatal | MedDRA V17.0 | 12 Day(s) |
| Foetal exposure during pregnancy | MedDRA V17.0 | 4 Month(s) |
| Premature baby | MedDRA V17.0 | |
| Small for dates baby | MedDRA V17.0 | 1 Day(s) |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000497106 | 0 | 2013-01-25 | 2013-01-25 | MAH | RB353282011 | Spontaneous | Physician | CANADA |

| Record Type | Link Aer Number |
|---|---|
| Linked | 000497065 |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 28 Years | Female | | | Recovered/resolved |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| NICOTINE | Suspect | NOT SPECIFIED | Unknown | 12 Dosage forms | 1 every 1 Day(s) | |
| OPIOIDS | Suspect | | Unknown | | | |
| SUBUTEX | Suspect | TABLET | Oral | 16 Milligram | 1 every 1 Day(s) | 87 Day(s) |
| CIPRALEX | Concomitant | TABLET | | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Exposure during pregnancy | MedDRA V17.0 | 4 Month(s) |
| Foetal growth restriction | MedDRA V17.0 | 1 Day(s) |

## No Duplicate or Linked Reports

### Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000429848 | 1 | 2012-04-17 | 2012-11-30 | MAH | CAJNJFOC20120405092 | Spontaneous | Pharmacist | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CONCERTA | Suspect | TABLET (EXTENDED-RELEASE) | Oral | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000434249 | 0 | 2012-05-03 | 2012-05-03 | MAH | CAN20120002951 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 36 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000436071 | 0 | 2012-05-09 | 2012-05-09 | MAH | CAN20120002981 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Inhalation | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000436083 | 2 | 2012-05-09 | 2013-09-16 | MAH | CAN-2012-0002977 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 31 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug abuse | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000436938 | 0 | 2012-05-11 | 2012-05-11 | MAH | CAN20120002993 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 18 Years | Male | | | Death |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANTIDEPRESSANTS | Suspect | NOT SPECIFIED | Unknown | | | |
| ANTIPSYCHOTIC(S) | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| TYLENOL | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Suicidal behaviour | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000438410 | 0 | 2012-05-22 | 2012-05-22 | MAH | CAN20120003023 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| COCAINE | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| LYSERGIDE | Suspect | | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| MDMA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | 8 Milligram | 1 every 1 Day(s) | |
| PERCOCET | Suspect | TABLET | Unknown | | | |
| PSILOCYBIN | Suspect | | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Decreased appetite | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Feeling of relaxation | MedDRA V17.0 | |
| Insomnia | MedDRA V17.0 | |
| Mental disorder | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Suicidal behaviour | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000439813 | 0 | 2012-05-25 | 2012-05-25 | MAH | CAN20120003032 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Death |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Coordination abnormal | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000441833 | 1 | 2012-06-05 | 2012-07-25 | MAH | CAN20120003064 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 28 Years | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Unknown | 6 Dosage forms | 1 every 1 Day(s) | 40 Day(s) |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug abuse | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug tolerance | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000441882 | 0 | 2012-06-05 | 2012-06-05 | MAH | CAN20120003062 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 38 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | Unknown | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | Unknown | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000442709 | 0 | 2012-06-08 | 2012-06-08 | MAH | CAN20120003073 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CODEINE | Suspect | TABLET | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000444782 | 0 | 2012-06-15 | 2012-06-15 | MAH | CAN20120003092 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug abuse | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000448863 | 0 | 2012-07-05 | 2012-07-05 | MAH | CAN20120003157 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 22 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000449049 | 0 | 2012-07-06 | 2012-07-06 | MAH | CAJNJFOC20120613045 | Study | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Female | | 55 Kilograms | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| REMICADE | Suspect | POWDER FOR SOLUTION INTRAVENOUS | Intravenous (not otherwise specified) | 300 Milligram | 1 every 6 Week(s) | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Dizziness | MedDRA V17.0 | |
| Hyperhidrosis | MedDRA V17.0 | |
| Hypotension | MedDRA V17.0 | |
| Loss of consciousness | MedDRA V17.0 | |
| Pallor | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000450531 | 0 | 2012-07-13 | 2012-07-13 | MAH | CAN20120003170 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 17 Years | Female | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANTIDEPRESSANTS | Suspect | NOT SPECIFIED | Unknown | | | |
| CODEINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| TYLENOL WITH CODEINE NO. 3 - TAB | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Mental impairment | MedDRA V17.0 | |
| Stab wound | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer.No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000454673 | 0 | 2012-07-31 | 2012-07-31 | MAH | CAN20120003205 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 27 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE HYDROCHLORIDE INJECTION USP | Suspect | SOLUTION INTRAMUSCULAR | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000455186 | 0 | 2012-08-02 | 2012-08-02 | MAH | CAN20120003218 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 21 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000455189 | 0 | 2012-08-02 | 2012-08-02 | MAH | CAN20120003215 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000455599 | 0 | 2012-08-07 | 2012-08-07 | MAH | CAN20120003221 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 21 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| STEROID | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000456737 | 0 | 2012-08-10 | 2012-08-10 | MAH | CAN20120003233 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 27 Years | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| NICOTINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000460163 | 0 | 2012-08-30 | 2012-08-30 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: N/A | Disability: N/A | Congenital Anomaly: N/A |
|---|---|---|---|
| No | Life Threatening: N/A | Hospitalization: N/A | Other Medically Imp Condition: N/A |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Not specified | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Unknown | | Once | Once |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Diarrhoea | MedDRA V17.0 | |
| Headache | MedDRA V17.0 | |
| Hyperhidrosis | MedDRA V17.0 | |
| Tremor | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000460675 | 0 | 2012-08-28 | 2012-08-28 | MAH | CAN20120003269 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 25 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000461609 | 0 | 2012-08-30 | 2012-08-30 | MAH | CAN20120003272 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 31 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000461937 | 0 | 2012-08-30 | 2012-08-30 | MAH | CAN20120003279 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000463562 | 0 | 2012-09-07 | 2012-09-07 | MAH | CAN20120003302 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 22 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000464601 | 0 | 2012-09-14 | 2012-09-14 | MAH | CAN20120003329 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 30 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

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## Report Information

| Aer.No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000465561 | 1 | 2012-09-18 | 2012-10-09 | MAH | 12P028097651400 | Study | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 36 Years | Male | | 136 Pounds | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| HUMIRA | Suspect | SOLUTION SUBCUTANEOUS | Subcutaneous | 40 Milligram | 1 every 2 Week(s) | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| PANTOLOC | Concomitant | TABLET (ENTERIC-COATED) | | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aphagia | MedDRA V17.0 | |
| Cerebrosclerosis | MedDRA V17.0 | |
| Dehydration | MedDRA V17.0 | |
| Demyelination | MedDRA V17.0 | |
| Dizziness | MedDRA V17.0 | |
| Dysarthria | MedDRA V17.0 | |
| Dysphagia | MedDRA V17.0 | |
| Feeling abnormal | MedDRA V17.0 | |
| Fluid intake reduced | MedDRA V17.0 | |
| Grand mal convulsion | MedDRA V17.0 | |
| Migraine | MedDRA V17.0 | |
| Staring | MedDRA V17.0 | |
| Vertigo | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000465738 | 0 | 2012-09-18 | 2012-09-18 | MAH | CAN20120003331 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 33 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | TABLET | Intravenous (not otherwise specified) | 50 Dosage forms | 1 every 1 Day(s) | |
| HEROIN | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OPIOID (S) | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Acquired immunodeficiency syndrome | MedDRA V17.0 | |
| Convulsion | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000466284 | 0 | 2012-09-20 | 2012-09-20 | MAH | CAN20120003344 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 47 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Oral | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000466289 | 0 | 2012-09-20 | 2012-09-20 | MAH | CAN20120003349 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000466307 | 1 | 2012-09-20 | 2012-09-27 | MAH | CAN20120003342 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 23 Years | Male | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| HEROIN | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abdominal pain upper | MedDRA V17.0 | |
| Depressed mood | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Pain | MedDRA V17.0 | |
| Skin discolouration | MedDRA V17.0 | |
| Somnolence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |
| Withdrawal syndrome | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000466984 | 0 | 2012-09-24 | 2012-09-24 | MAH | CAN20120003351 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 24 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000471374 | 1 | 2012-10-17 | 2012-11-13 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 66 Years | Female | 157 Centimetres | 165 Pounds | Recovered/resolved with sequelae |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Oral | 1 Dosage forms | Once | Once |
| ALMOND MILK | Concomitant | | | | | |
| CALCIUM & MAGNESIUM WITH VITAMIN D | Concomitant | NOT SPECIFIED | | | | |
| MULTIVITAMINE(S) | Concomitant | NOT SPECIFIED | | | | |
| VITAMIN B COMPLEX | Concomitant | NOT SPECIFIED | | | | |
| VITAMIN C | Concomitant | NOT SPECIFIED | | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abdominal pain upper | MedDRA V17.0 | 32 Day(s) |
| Asthenia | MedDRA V17.0 | 32 Day(s) |
| Dehydration | MedDRA V17.0 | 32 Day(s) |
| Diarrhoea | MedDRA V17.0 | 32 Day(s) |
| Haemorrhoids | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | 32 Day(s) |
| Nausea | MedDRA V17.0 | 32 Day(s) |
| Pain | MedDRA V17.0 | 32 Day(s) |
| Vomiting | MedDRA V17.0 | 32 Day(s) |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000473205 | 0 | 2012-10-18 | 2012-10-18 | MAH | CAN20120003407 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 42 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000474963 | 0 | 2012-10-26 | 2012-10-26 | MAH | 8162 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| No | N/A | N/A | N/A |
| | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |
| | N/A | N/A | N/A |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | | | Recovered/resolved |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Oral | 39.7 Gram | 1 every 1 Day(s) | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abdominal pain | MedDRA V17.0 | |
| Abdominal pain upper | MedDRA V17.0 | |
| Diarrhoea | MedDRA V17.0 | |

### Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000479197 | 0 | 2012-11-06 | 2012-11-06 | MAH | CAN20120003466 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 24 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ADDERALL XR | Suspect | CAPSULE, EXTENDED RELEASE | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Intra-nasal | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Chills | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000479871 | 0 | 2012-11-09 | 2012-11-09 | MAH | CAN20120003486 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 21 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000479875 | 0 | 2012-11-09 | 2012-11-09 | MAH | CAN20120003492 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 24 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Feeling of despair | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Suicidal behaviour | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000483488 | 0 | 2012-11-22 | 2012-11-22 | MAH | CAN20120003523 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 15 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000483491 | 0 | 2012-11-22 | 2012-11-22 | MAH | CAN20120003519 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 32 Years | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| AMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPH CONTIN | Suspect | CAPSULE, SUSTAINED-RELEASE | Intra-nasal | | | |
| HYDROMORPH CONTIN | Suspect | CAPSULE, SUSTAINED-RELEASE | Intravenous (not otherwise specified) | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Unknown | | | |
| LSD | Suspect | | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| MESCALINE | Suspect | | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| NICOTINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Intravenous (not otherwise specified) | | | |
| PSILOCYBINE | Suspect | | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Antisocial behaviour | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Emotional poverty | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Exposure to contaminated device | MedDRA V17.0 | |
| Fatigue | MedDRA V17.0 | |
| Flushing | MedDRA V17.0 | |
| Hyperhidrosis | MedDRA V17.0 | |
| Nausea | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000484271 | 1 | 2012-11-23 | 2012-12-13 | MAH | CAN20120003530 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| ANTIPSYCHOTIC(S) | Concomitant | NOT SPECIFIED | | | | |
| RITALIN | Concomitant | NOT SPECIFIED | | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Anger | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Insomnia | MedDRA V17.0 | |
| Somnolence | MedDRA V17.0 | |
| Stress | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000486984 | 0 | 2012-12-06 | 2012-12-06 | MAH | CAN20120003561 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 40 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| AMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| LSD | Suspect | | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000488755 | 1 | 2012-12-13 | 2013-01-15 | MAH | 2012BI057652 | Spontaneous | Physician | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | | Congenital Anomaly: | |
|---|---|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Yes | Other Medically Imp Condition: | Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 24 Years | Female | | | Recovering/resolving |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ALPRAZOLAM | Suspect | TABLET | Unknown | | | |
| AMITRIPTYLINE | Suspect | TABLET | Unknown | | | |
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| TRAMACET | Suspect | TABLET | Unknown | | | |
| TYLENOL | Suspect | NOT SPECIFIED | Unknown | | | |
| TYSABRI | Suspect | SOLUTION INTRAVENOUS | Intravenous (not otherwise specified) | 300 Milligram | 1 every 1 Month(s) | |
| CHAMPIX | Concomitant | TABLET | | | | |
| TRI-CYCLEN TABLETS - 28-DAY | Concomitant | TABLET | | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Convulsion | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Suicide attempt | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000489264 | 0 | 2012-12-14 | 2012-12-14 | MAH | CAN20120003582 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 41 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000494506 | 0 | 2013-01-14 | 2013-01-14 | MAH | CAN20130003636 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 34 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYNEO | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000495573 | 2 | 2013-01-18 | 2013-02-01 | MAH | CAN20130003651 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 55 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| AMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Toxicity to various agents | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000499698 | 0 | 2013-02-07 | 2013-02-07 | MAH | CAN20130003733 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | 5 Milligram | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000501406 | 2 | 2013-02-12 | 2013-03-04 | MAH | 13P028104537900 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| BIAXIN XL | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | 1000 Milligram | 1 every 1 Day(s) | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| UNSPECIFIED SYRUP | Suspect | | Unknown | | | |
| NASONEX | Concomitant | SPRAY, METERED DOSE | | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abnormal behaviour | MedDRA V17.0 | |
| Aggression | MedDRA V17.0 | |
| Anger | MedDRA V17.0 | |
| Anxiety | MedDRA V17.0 | |
| Cataract | MedDRA V17.0 | |
| Confusional state | MedDRA V17.0 | |
| Cough | MedDRA V17.0 | |
| Crying | MedDRA V17.0 | |
| Delusion of grandeur | MedDRA V17.0 | |
| Disorientation | MedDRA V17.0 | |
| Disturbance in attention | MedDRA V17.0 | |
| Dreamy state | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Eye injury | MedDRA V17.0 | |
| Feeling abnormal | MedDRA V17.0 | |
| Hallucination, auditory | MedDRA V17.0 | |
| Hallucination, visual | MedDRA V17.0 | |
| Insomnia | MedDRA V17.0 | |
| Laceration | MedDRA V17.0 | |
| Nausea | MedDRA V17.0 | |
| Ocular hyperaemia | MedDRA V17.0 | |
| Pain | MedDRA V17.0 | |

| | | |
|---|---|---|
| Photophobia | MedDRA V17.0 | |
| Procedural haemorrhage | MedDRA V17.0 | |
| Psychotic disorder | MedDRA V17.0 | |
| Pupillary deformity | MedDRA V17.0 | |
| Somnolence | MedDRA V17.0 | |
| Speech disorder | MedDRA V17.0 | |
| Thinking abnormal | MedDRA V17.0 | |
| Visual acuity reduced | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000501704 | 0 | 2013-02-13 | 2013-02-13 | MAH | CAN20130003747 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000501714 | 0 | 2013-02-13 | 2013-02-13 | MAH | CAN20130003742 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| VALIUM 5 TAB | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Hyperhidrosis | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Withdrawal syndrome | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000501773 | 0 | 2013-02-13 | 2013-02-13 | MAH | CAN20130003745 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 52 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CODEINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |
| PSILOCYBIN | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000502306 | 0 | 2013-02-15 | 2013-02-15 | MAH | CAN20130003765 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 26 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| FENTANYL | Suspect | PATCH | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000502949 | 0 | 2013-02-20 | 2013-02-20 | MAH | CAN20130003777 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANALGESICS | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Depression | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000502951 | 0 | 2013-02-20 | 2013-02-20 | MAH | CAN20130003778 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 32 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Inhalation | | | |
| CODEINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505761 | 1 | 2013-03-05 | 2013-03-08 | MAH | CAJNJFOC20130214849 | Spontaneous | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 16 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CONCERTA | Suspect | TABLET (EXTENDED-RELEASE) | Oral | 27 Milligram | 1 every 1 Day(s) | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | 3 every 1 Day(s) | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Insomnia | MedDRA V17.0 | |
| Poor personal hygiene | MedDRA V17.0 | |
| Psychomotor hyperactivity | MedDRA V17.0 | |
| Restlessness | MedDRA V17.0 | |
| Thinking abnormal | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505880 | 1 | 2013-03-05 | 2013-05-13 | MAH | CAN-2013-0003820 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: Yes | Hospitalization: Yes | Other Medically Imp Condition: |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 49 Years | Female | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| CODEINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHADONE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Confusional state | MedDRA V17.0 | |
| Consciousness fluctuating | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Dysarthria | MedDRA V17.0 | |
| Dyspnoea | MedDRA V17.0 | |
| Gait disturbance | MedDRA V17.0 | |
| Hypotension | MedDRA V17.0 | |
| Judgement impaired | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Toxicity to various agents | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505886 | 0 | 2013-03-05 | 2013-03-05 | MAH | CAN20130003800 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 21 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANTIDEPRESSANTS | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| COCAINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Injection site haematoma | MedDRA V17.0 | |
| Injection site scar | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Suicide attempt | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000505901 | 0 | 2013-03-05 | 2013-03-05 | MAH | CAN20130003824 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 28 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000506918 | 0 | 2013-03-07 | 2013-03-07 | MAH | 8233 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| No | N/A | N/A | N/A |
| | Life Threatening: N/A | Hospitalization: N/A | Other Medically Imp Condition: N/A |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | | | Recovered/resolved |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Unknown | 1 Dosage forms | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abdominal discomfort | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000507507 | 0 | 2013-03-11 | 2013-03-11 | MAH | CAN20130003839 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |

### Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000508733 | 0 | 2013-03-18 | 2013-03-18 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| No | N/A | N/A | N/A |

| Life Threatening: | Hospitalization: | Other Medically Imp Condition: |
|---|---|---|
| N/A | N/A | N/A |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 49 Years | Female | 157 Centimetres | 130 Pounds | Recovered/resolved |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA SPORT PERFORMANCE PROTEIN | Suspect | POWDER | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Chills | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000513226 | 0 | 2013-03-28 | 2013-03-28 | MAH | CAN20130003947 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 36 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000513645 | 0 | 2013-04-02 | 2013-04-02 | MAH | CAN20130003949 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 49 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Unknown | | | |
| TABACUM | Suspect | GLOBULES ORAL | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000513646 | 0 | 2013-04-02 | 2013-04-02 | MAH | CAN20130003956 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 31 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Energy increased | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000514772 | 0 | 2013-04-03 | 2013-04-03 | MAH | CAN20130003960 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 29 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Inhalation | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| NICOTINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Intra-nasal | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Intravenous (not otherwise specified) | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Localised infection | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Tooth extraction | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000517012 | 0 | 2013-04-17 | 2013-04-17 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | N/A | Disability: | N/A | Congenital Anomaly: | N/A |
|---|---|---|---|---|---|---|
| No | Life Threatening: | N/A | Hospitalization: | N/A | Other Medically Imp Condition: | N/A |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | 167 Centimetres | 64 Kilograms | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Nausea | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000523443 | 0 | 2013-05-06 | 2013-05-06 | MAH | CAN20130004103 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| LSD | Suspect | | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Inhalation | | | |
| PSILOCYBIN | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000524153 | 0 | 2013-05-07 | 2013-05-07 | MAH | CAN20130004104 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ECSTASY | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Intravenous (not otherwise specified) | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Malaise | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000525202 | 0 | 2013-05-10 | 2013-05-10 | MAH | CAN20130004123 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000525206 | 0 | 2013-05-10 | 2013-05-10 | MAH | CAN20130004132 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Intra-nasal | | | |
| PERCOCET | Suspect | TABLET | Inhalation | | | |
| PERCOCET | Suspect | TABLET | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000526739 | 1 | 2013-05-16 | 2013-11-18 | MAH | CAN-2013-0004162 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 17 Years | Male | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Intra-nasal | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Accidental overdose | MedDRA V17.0 | |
| Brain death | MedDRA V17.0 | |
| Brain hypoxia | MedDRA V17.0 | |
| Dyspnoea | MedDRA V17.0 | |
| Feeling abnormal | MedDRA V17.0 | |
| Loss of consciousness | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Vomiting | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000529094 | 0 | 2013-05-24 | 2013-05-24 | MAH | CAN20130004185 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| LSD (LYSERGIDE) | Suspect | | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000529553 | 0 | 2013-05-27 | 2013-05-27 | MAH | CAN20130004197 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 22 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000530034 | 0 | 2013-05-29 | 2013-05-29 | MAH | CAN20130004200 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000530720 | 2 | 2013-05-31 | 2013-07-19 | MAH | PHHO2013CA006676 | Study | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 52 Years | Male | | 125.4 Kilograms | Recovering/resolving |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| FENTANYL | Suspect | PATCH | Unknown | 25 Microgram | 1 every 72 Hour(s) | |
| MARIJUANA | Suspect | NOT SPECIFIED | Subcutaneous | 2 Gram | 1 every 1 Day(s) | |
| STUDY DRUG | Suspect | NOT SPECIFIED | Subcutaneous | | | |
| AMLODIPINE | Concomitant | TABLET | | | | |
| CRESTOR | Concomitant | TABLET | | | | |
| ELTROXIN | Concomitant | TABLET | | | | |
| LORAZEPAM | Concomitant | NOT SPECIFIED | | | | |
| NICOTINE | Concomitant | NOT SPECIFIED | | | | |
| OLANZAPINE | Concomitant | NOT SPECIFIED | | | | |
| PANTOLOC | Concomitant | TABLET (ENTERIC-COATED) | | | | |
| RAMIPRIL | Concomitant | NOT SPECIFIED | | | | |
| RESERPINE | Concomitant | NOT SPECIFIED | | | | |
| TRAZODONE | Concomitant | TABLET | | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Analgesic drug level decreased | MedDRA V17.0 | |
| Blood glucose increased | MedDRA V17.0 | |
| Blood thyroid stimulating hormone increased | MedDRA V17.0 | |
| Psychotic disorder | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000531316 | 0 | 2013-06-04 | 2013-06-04 | MAH | CAN-2013-0004217 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 32 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Dysarthria | MedDRA V17.0 | |
| Injury | MedDRA V17.0 | |
| Pupillary reflex impaired | MedDRA V17.0 | |
| Road traffic accident | MedDRA V17.0 | |
| Somnolence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Tremor | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000532751 | 0 | 2013-06-07 | 2013-06-07 | MAH | CAN20130004224 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Unknown | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000533830 | 0 | 2013-06-12 | 2013-06-12 | MAH | CAN20130004239 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MDMA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |
| RITALIN | Suspect | NOT SPECIFIED | Unknown | | | |
| SLEEPING PILL(S) | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Infection | MedDRA V17.0 | |
| Jaundice | MedDRA V17.0 | |
| Liver injury | MedDRA V17.0 | |
| Mobility decreased | MedDRA V17.0 | |
| Oedema peripheral | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000533841 | 0 | 2013-06-12 | 2013-06-12 | MAH | CAN20130004232 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 39 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Alcohol poisoning | MedDRA V17.0 | |
| Memory impairment | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000534616 | 0 | 2013-06-14 | 2013-06-14 | MAH | CAN20130004245 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 27 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

### Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000535840 | 0 | 2013-06-20 | 2013-06-20 | MAH | CAN-2013-0004248 | Spontaneous | Other Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: Yes | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 19 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| HYDROMORPH CONTIN | Suspect | CAPSULE, SUSTAINED-RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Judgement impaired | MedDRA V17.0 | |
| Psychomotor skills impaired | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000540560 | 1 | 2013-07-11 | 2013-08-08 | MAH | CAN-2013-0004283 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 27 Years | Male | 178 Centimetres | 254 Pounds | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANABOLIC STEROID | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| ANABOLIC STEROID | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000542632 | 0 | 2013-07-22 | 2013-07-22 | MAH | CAN-2013-0004302 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 22 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPH CONTIN | Suspect | CAPSULE, SUSTAINED-RELEASE | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHADONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Impaired driving ability | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Toxicity to various agents | MedDRA V17.0 | |

## Report Information

| Aer No. | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000544630 | 0 | 2013-07-29 | 2013-07-29 | MAH | CAN20130004310 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 18 Years | Male | | 54.42 Kilograms | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MDMA | Suspect | NOT SPECIFIED | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug abuse | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Insomnia | MedDRA V17.0 | |
| Multi-organ failure | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000544800 | 0 | 2013-07-30 | 2013-07-30 | MAH | CAN-2013-0004318 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 23 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000544919 | 0 | 2013-07-30 | 2013-07-30 | MAH | CAN20130004317 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 22 Years | Female | 63 Inches | 35.37 Kilograms | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| AMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE HCL TAB 4MG USP | Suspect | TABLET | Unknown | | | |
| METHAMPHETAMINE | Suspect | NOT SPECIFIED | Unknown | | | |
| OPIOID (S) | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Aggression | MedDRA V17.0 | |
| Cardiac failure | MedDRA V17.0 | |
| Cold sweat | MedDRA V17.0 | |
| Conversion disorder | MedDRA V17.0 | |
| Convulsion | MedDRA V17.0 | |
| Decreased appetite | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Pain | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |
| Tremor | MedDRA V17.0 | |
| Weight decreased | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000550287 | 0 | 2013-08-22 | 2013-08-22 | MAH | CAN-2013-0004364 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 21 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| HYDROMORPHONE HCL TAB 4MG USP | Suspect | TABLET | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| PERCOCET | Suspect | TABLET | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Memory impairment | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000553034 | 0 | 2013-09-05 | 2013-09-05 | MAH | CAN-2013-0004390 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: Yes | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 16 Years | Male | | | Death |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| HEROIN | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Overdose | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000556989 | 0 | 2013-09-23 | 2013-09-23 | MAH | CAN-2013-0004442 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 30 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| PHENCYCLIDINE | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000556992 | 0 | 2013-09-23 | 2013-09-23 | MAH | CAN-2013-0004449 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: | |
|---|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: | Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| PHENCYCLIDINE | Suspect | | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000559890 | 1 | 2013-10-02 | 2013-10-07 | MAH | CAN-2013-0004470 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 31 Years | Male | | | Unknown |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| HEROIN | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000560757 | 0 | 2013-10-04 | 2013-10-04 | MAH | CAN-2013-0004472 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 32 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Inhalation | | | |
| COCAINE | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| DRUGS | Suspect | | Intravenous (not otherwise specified) | | | |
| HEROIN | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OPIOID(S) | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000569036 | 0 | 2013-11-06 | 2013-11-06 | MAH | CAN-2013-0004531 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 38 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ANABOLIC STEROID | Suspect | NOT SPECIFIED | Unknown | | | |
| ANALGESICS | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

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## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000569335 | 0 | 2013-11-15 | 2013-11-15 | Community | | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| No | N/A | N/A | N/A |
| | **Life Threatening:** N/A | **Hospitalization:** N/A | **Other Medically Imp Condition:** N/A |

## Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 64 Years | Female | 62 Inches | 100 Pounds | Recovered/resolved |

## Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| VEGA ONE | Suspect | POWDER | Unknown | | 1 every 1 Day(s) | |

## Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Abdominal pain | MedDRA V17.0 | |
| Flatulence | MedDRA V17.0 | |
| Nausea | MedDRA V17.0 | |

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## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000571918 | 0 | 2013-11-18 | 2013-11-18 | MAH | CAN-2013-0004552 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 36 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Unknown | | | |
| PERCOCET | Suspect | TABLET | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000572408 | 1 | 2013-11-20 | 2014-03-24 | MAH | CAN-2013-0004557 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Inhalation | | | |
| COCAINE | Suspect | NOT SPECIFIED | Intra-nasal | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Anger | MedDRA V17.0 | |
| Crying | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Erythema | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Hyperhidrosis | MedDRA V17.0 | |
| Incoherent | MedDRA V17.0 | |
| Mental impairment | MedDRA V17.0 | |
| Overweight | MedDRA V17.0 | |
| Poisoning | MedDRA V17.0 | |
| Speech disorder | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000572410 | 0 | 2013-11-20 | 2013-11-20 | MAH | CAN-2013-0004559 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 23 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| HYDROMORPHONE | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MDMA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |
| OPIOID(S) | Suspect | NOT SPECIFIED | Intravenous (not otherwise specified) | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Chills | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug withdrawal syndrome | MedDRA V17.0 | |
| Euphoric mood | MedDRA V17.0 | |
| Lacrimation increased | MedDRA V17.0 | |
| Nausea | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000574200 | 1 | 2013-11-28 | 2014-03-24 | MAH | CAN-2013-0004569 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 20 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| DILAUDID | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Drug diversion | MedDRA V17.0 | |
| Epilepsy | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000576377 | 0 | 2013-12-05 | 2013-12-05 | MAH | CAN-2013-0004577 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 24 Years | Female | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Unknown | | | |
| MORPHINE SULFATE | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCONTIN | Suspect | TABLET (EXTENDED-RELEASE) | Unknown | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Drug dependence | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000577469 | 0 | 2013-12-10 | 2013-12-10 | MAH | CAN-2013-0004595 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000577862 | 2 | 2013-12-12 | 2014-05-30 | MAH | CAN-2013-0004593 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 60 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| ETHANOL | Suspect | NOT SPECIFIED | Unknown | | | |
| MARIJUANA | Suspect | NOT SPECIFIED | Inhalation | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Intra-nasal | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Alcohol poisoning | MedDRA V17.0 | |
| Drug dependence | MedDRA V17.0 | |
| Drug diversion | MedDRA V17.0 | |
| Substance abuse | MedDRA V17.0 | |

## Report Information

| Aer No | Version No. | Initial Rec. Date | Latest Rec. Date | Report Source | MAH Number | Type of Report | Reporter Type | Country |
|---|---|---|---|---|---|---|---|---|
| 000577864 | 0 | 2013-12-12 | 2013-12-12 | MAH | CAN-2013-0004597 | Spontaneous | Consumer Or Other Non Health Professional | CANADA |

| Record Type | Link Aer Number |
|---|---|
| No Duplicate or Linked Reports | |

| Serious Report? | Death: | Disability: | Congenital Anomaly: |
|---|---|---|---|
| Yes | Life Threatening: | Hospitalization: | Other Medically Imp Condition: Yes |

### Patient Information

| Age | Gender | Height | Weight | Report Outcome |
|---|---|---|---|---|
| 60 Years | Male | | | Unknown |

### Product Information

| Product Description | Product Role | Dosage Form | Route | Dosing | Frequency | Therapy Duration |
|---|---|---|---|---|---|---|
| CANNABIS | Suspect | NOT SPECIFIED | Unknown | | | |
| COCAINE | Suspect | NOT SPECIFIED | Unknown | | | |
| ETHANOL | Suspect | NOT SPECIFIED | Oral | | | |
| MDMA | Suspect | NOT SPECIFIED | Unknown | | | |
| OXYCODONE | Suspect | NOT SPECIFIED | Oral | | | |

### Reaction Information

| MedDRA Preferred Term | MedDRA Version | Duration |
|---|---|---|
| Substance abuse | MedDRA V17.0 | |