PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

[N] SANDOZ OPIUM & BELLADONNA®

Opium and Belladonna Suppository

Opium 65 mg, and belladonna 15 mg suppository

Analgesic - Antispasmodic

Sandoz Canada Inc.
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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Nonmedicinal Ingredients
Rectal	Suppository, each contains: opium 65 mg, and belladonna, 15 mg	Lactose anhydrous and Covi-Ox T70 (mixed Tocopherol)

INDICATIONS AND CLINICAL USE

Adults

Sandoz Opium & Belladonna is indicated for the relief of moderate to severe pain associated with ureteral spasm that is not responsive to non-opioid analgesics.

Geriatrics (> 65 years of age)

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, concomitant disease or other drug therapy (see ACTION AND CLINICAL PHARMACOLOGY, Special Populations and Conditions, Geriatrics).

Pediatrics (< 18 years of age)

The safety and efficacy of Opium and Belladonna suppository has not been studied in the pediatric population. Therefore the use of Sandoz Opium & Belladonna is not recommended in patients under 18 years of age.

CONTRAINDICATIONS

Sandoz Opium & Belladonna is contraindicated in:

- Patients with advanced renal or hepatic disease, acute alcoholism, delirium tremens, idiosyncrasy, convulsive disorders
- Patients with severe CNS depression, increased cerebrospinal or intracranial pressure, and head injury.

- patients with angle-closure glaucoma; however, antimuscarinics can be administered safely to patients with open-angle glaucoma who are being treated with miotics.
- patients with obstructive uropathy (e.g. bladder neck obstruction caused by prostatic hypertrophy).
- patients with severe ulcerative colitis or toxic megacolon complicating ulcerative colitis.
- patients with obstructive disease of the GI tract (e.g. pyloroduodenal stenosis, achalasia, cardiospasm, paralytic ileus, or intestinal atony (especially in geriatric or debilitated patients)
- In patients with known or suspected mechanical gastrointestinal obstruction (e.g., bowel obstruction or strictures) or any diseases/conditions that affect bowel transit (e.g., ileus of any type).
- Patients with suspected surgical abdomen (e.g., acute appendicitis or pancreatitis).
- patients with myasthenia gravis unless the antimuscarinic is used to reduce adverse muscarinic effects of an anticholinesterase agent (e.g. neostigmine).
- the presence of tachycardia secondary to cardiac insufficiency or thyrotoxicosis.
- patients with acute haemorrhage whose cardiovascular status is unstable.
- Patients who are hypersensitive to the active substance Opium and Belladonna or other opioid analgesics or to any ingredient in the formulation. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section of the Product Monograph.
- Patients with mild pain that can be managed with other pain medications.
- Patients with acute or severe bronchial asthma, chronic obstructive airway, or status asthmaticus.
- Patients with acute respiratory depression, elevated carbon dioxide levels in the blood and cor pulmonale.
- Patients taking monoamine oxidase (MAO) inhibitors (or within 14 days of such therapy).
- Women in premature labour

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the risks of overdose and death with immediate release opioid formulations, Sandoz Opium & Belladonna (suppository) should only be used in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate to provide appropriate management of pain (see DOSAGE AND ADMINISTRATION).

Addiction, Abuse, and Misuse

Sandoz Opium & Belladonna poses risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Each patient's risk should be assessed prior to prescribing Sandoz Opium & Belladonna, and all patients should be monitored regularly for the development of these behaviours or conditions (see WARNINGS AND PRECAUTIONS). Sandoz Opium & Belladonna should be stored securely to avoid theft or misuse.

Life-threatening Respiratory Depression: OVERDOSE

Serious, life-threatening, or fatal respiratory depression may occur with use of Sandoz Opium & Belladonna. Infants exposed in-utero or through breast milk are at risk of life-threatening respiratory depression upon delivery or when nursed. Patients should be monitored for respiratory depression, especially during initiation of Sandoz Opium & Belladonna or following a dose increase.

Sandoz Opium & Belladonna must be inserted whole. Cutting, breaking, crushing, chewing, or dissolving Sandoz Opium & Belladonna can lead to dangerous adverse events including death (see WARNINGS AND PRECAUTIONS). Further, instruct patients of the hazards related to taking opioids including fatal overdose.

Accidental Exposure

Accidental ingestion of even one dose of Sandoz Opium & Belladonna, especially by children, can result in a fatal overdose of Opium and Belladonna suppository (see DOSAGE AND ADMINISTRATION, Disposal, for instructions on proper disposal).

Neonatal Opioid Withdrawal Syndrome

Prolonged maternal use of Sandoz Opium & Belladonna during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening (see WARNINGS AND PRECAUTIONS).

Interaction with Alcohol

The co-ingestion of alcohol with Sandoz Opium & Belladonna should be avoided as it may result in dangerous additive effects, causing serious injury or death (see WARNINGS AND PRECAUTIONS and DRUG INTERACTIONS).

Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death (see WARNINGS AND PRECAUTIONS, Neurologic and DRUG INTERACTIONS).

- **Reserve concomitant prescribing of Sandoz Opium & Belladonna and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

General

When preparations containing combination of drugs are administered, the cautions applicable to each ingredient should be borne in mind. Antimuscarinics share the toxic potential of atropine, and the usual precautions associated with atropine therapy should be observed with these agents.

Patients should be instructed not to give Sandoz Opium & Belladonna (Opium and Belladonna suppository) to anyone other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death. Sandoz Opium & Belladonna should be stored securely to avoid theft or misuse.

Sandoz Opium & Belladonna should only be prescribed by persons knowledgeable in the continuous administration of potent opioids, in the management of patients receiving potent opioids for the treatment of pain, and in the detection and management of respiratory depression, including the use of opioid antagonists.

Patients should be cautioned not to consume alcohol while taking **Sandoz Opium & Belladonna** as it may increase the chance of experiencing serious adverse events, including death.

Hyperalgesia that will not respond to a further dose increase of Opium and Belladonna suppository can occur at particularly high doses. An Opium and Belladonna suppository dose reduction or change in opioid may be required.

Abuse and Misuse

Like all opioids, **Sandoz Opium & Belladonna** is a potential drug of abuse and misuse, which can lead to overdose and death. Therefore, **Sandoz Opium & Belladonna** should be prescribed and handled with caution.

Patients should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids. All patients receiving opioids should be routinely monitored for signs of misuse and abuse.

Opioids, such as **Sandoz Opium & Belladonna**, should be used with particular care in patients with a history of alcohol and illicit/prescription drug abuse. However, concerns about abuse, addiction, and diversion should not prevent the proper management of pain.

Sandoz Opium & Belladonna suppositories should be inserted whole, not crushed or cut, and should not be chewed. Abuse of the dosage form can be expected to result in serious adverse events, including death.

Cardiovascular

Opium administration may result in severe hypotension in patients whose ability to maintain adequate blood pressure is compromised by reduced blood volume, or concurrent administration of drugs such as phenothiazines and other tranquilizers, sedative/hypnotics, tricyclic antidepressants or general anesthetics. These patients should be monitored for signs of hypotension after initiating or titrating the dose of Sandoz Opium & Belladonna.

The use of **Sandoz Opium & Belladonna** in patients with circulatory shock should be avoided as it may cause vasodilation that can further reduce cardiac output and blood pressure.

Caution should be used in patients with atrial flutter and other supraventricular tachycardias due to a possible vagolytic action which may produce a significant increase in the ventricular

response rate.

Antimuscarinics such as belladonna block vagal inhibition of the SA nodal pacemaker and thus should be used with caution in patients with tachyarrhythmias, congestive heart failure, or coronary artery disease. Because of their cholinergic effects, opioid agonists should be used with caution in patients with cardiac arrhythmias.

Dependence/Tolerance

As with other opioids, tolerance and physical dependence may develop upon repeated administration of Sandoz Opium & Belladonna and there is a potential for development of psychological dependence.

Physical dependence and tolerance reflect the neuroadaptation of the opioid receptors to chronic exposure to an opioid, and are separate and distinct from abuse and addiction. Tolerance, as well as physical dependence, may develop upon repeated administration of opioids, and are not by themselves evidence of an addictive disorder or abuse.

Patients on prolonged therapy should be tapered gradually from the drug if it is no longer required for pain control. Withdrawal symptoms may occur following abrupt discontinuation of therapy or upon administration of an opioid antagonist. Some of the symptoms that may be associated with abrupt withdrawal of an opioid analgesic include body aches, diarrhea, gooseflesh, loss of appetite, nausea, nervousness or restlessness, anxiety, runny nose, sneezing, tremors or shivering, stomach cramps, tachycardia, trouble with sleeping, unusual increase in sweating, palpitations, unexplained fever, weakness and yawning (see ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, Adjustment or Reduction of Dosage).

Use in Drug and Alcohol Addiction

Sandoz Opium & Belladonna is an opioid with no approved use in the management of addictive disorders. Its proper usage in individuals with drug or alcohol dependence, either active or in remission is for the management of pain requiring opioid analgesia. Patients with a history of addiction to drugs or alcohol may be at higher risk of becoming addicted to Sandoz Opium & Belladonna; extreme caution and awareness is warranted to mitigate the risk.

Endocrine

Sandoz Opium & Belladonna suppositories are to be used with extreme caution, if at all, in patients with untreated myxedema. Care should be exercised and the initial dosage of the opioid agonist should be reduced in patients with hypothyroidism, or Addison's disease.

Adrenal Insufficiency

Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non-specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and

continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

Gastrointestinal

Opium and Belladonna suppository and other morphine-like opioids have been shown to decrease bowel motility. Care should be exercised in patients with disorders of the biliary tract because circulating opium may induce smooth muscle hypertonicity resulting in biliary colic. Opium & Belladonna suppository may obscure the diagnosis or clinical course of patients with acute abdominal conditions (see CONTRAINDICATIONS).

Antimuscarinics should be administered with extreme caution to patients with known or suspected GI infections (e.g. antibiotic-associated pseudomembranous colitis, shigellosis, dysentry), since these drugs may decrease GI motility and prolong symptomatology by causing retention of the causative organism or toxin(s). Antimuscarinics should be used with extreme caution in patients with mild to moderate ulcerative colitis, since antimuscarinics may suppress intestinal motility and produce paralytic ileus with resultant precipitation or aggravation of toxic megacolon.

Belladonna should be used with extreme caution in patients with acute enterocolitis.

Care should be exercised and the initial dosage of the opioid agonist should be reduced in patients who have undergone GI surgery.

Neonatal Opioid Withdrawal Syndrome (NOWS)

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening.

Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn.

Sandoz Opium & Belladonna is not recommended to be used in pregnant women unless, in the judgement of the physician, the potential benefits outweigh the risks. If **Sandoz Opium & Belladonna** was used during pregnancy, special attention to NOWS is warranted

Neurologic

Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol): Opium and Belladonna suppository should be used with caution and in a reduced dosage during concomitant administration of other opioid analgesics, general anesthetics, phenothiazines and other tranquilizers, sedative-hypnotics, tricyclic antidepressants,

antipsychotics, antihistamines, benzodiazepines, centrally-active anti-emetics and other CNS depressants. Respiratory depression, hypotension and profound sedation, coma or death may result.

Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioid analgesics alone. Because of similar pharmacological properties, it is reasonable to expect similar risk with the concomitant use of other CNS depressant drugs with opioid analgesics (see DRUG INTERACTIONS). If the decision is made to prescribe a benzodiazepine or other CNS depressant concomitantly with an opioid analgesic, prescribe the lowest effective dosages and minimum durations of concomitant use. In patients already receiving an opioid analgesic, prescribe a lower initial dose of the benzodiazepine or other CNS depressant than indicated in the absence of an opioid, and titrate based on clinical response. If an opioid analgesic is initiated in a patient already taking a benzodiazepine or other CNS depressant, prescribe a lower initial dose of the opioid analgesic, and titrate based on clinical response. Follow patients closely for signs and symptoms of respiratory depression and sedation.

Advise both patients and caregivers about the risks of respiratory depression and sedation when Sandoz Opium & Belladonna is used with benzodiazepines or other CNS depressants (including alcohol and illicit drugs). Advise patients not to drive or operate heavy machinery until the effects of concomitant use of the benzodiazepine or other CNS depressant have been determined. Screen patients for risk of substance use disorders, including opioid abuse and misuse, and warn them of the risk for overdose and death associated with the use of additional CNS depressants including alcohol and illicit drugs (see DRUG INTERACTIONS).

Sandoz Opium & Belladonna should not be used with alcohol as it may increase the chance of experiencing dangerous side effects, including death (see CONTRAINDICATIONS and ADVERSE REACTIONS, Sedation, and DRUG INTERACTIONS).

Severe pain antagonizes the subjective and respiratory depressant actions of opioid analgesics. Should pain suddenly subside, these effects may rapidly become manifest.

Head Injury: The respiratory depressant effects of Opium and Belladonna suppository, and the capacity to elevate cerebrospinal fluid pressure, may be greatly increased in the presence of an already elevated intracranial pressure produced by trauma. Also, Opium and Belladonna suppository may produce confusion, miosis, vomiting and other side effects which obscure the clinical course of patients with head injury. In such patients, Opium and Belladonna suppository must be used with extreme caution and only if it is judged essential (see CONTRAINDICATIONS**).**

Use in Patients with Convulsive or Seizure Disorders is Contraindicated: The **Sandoz Opium & Belladonna suppository** may aggravate convulsions in patients with convulsive disorders, and may induce or aggravate seizures in some clinical settings. Therefore, **Sandoz Opium & Belladonna** should not be used in these patients (see CONTRAINDICATIONS).

Use in Patients with Autonomic Neuropathy

Antimuscarinics such as belladonna should be used with extreme caution in patients with autonomic neuropathy.

Serotonin syndrome: Sandoz Opium & Belladonna could cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs (e.g. anti-depressants, migraine medications). Treatment with the serotonergic drug should be discontinued if such events (characterized by clusters of symptoms such as hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs, mental status changes including confusion, irritability, extreme agitation progressing to delirium and coma) occur and supportive symptomatic treatment should be initiated. **Sandoz Opium & Belladonna** should not be used in combination with MAO inhibitors or serotonin-precursors (such as L-tryptophan, oxitriptan) and should be used with caution in combination with other serotonergic drugs (triptans, certain tricyclic antidepressants, lithium, tramadol, St. John's Wort) due to the risk of serotonergic syndrome (see DRUG INTERACTIONS).

Peri-Operative Considerations

Sandoz Opium & Belladonna is not indicated for pre-emptive analgesia (administration pre-operatively for the management of post-operative pain).

Opium and Belladonna suppository and other morphine-like opioids have been shown to decrease bowel motility. Ileus is a common post-operative complication, especially after intra-abdominal surgery with opioid analgesia. Caution should be taken to monitor for decreased bowel motility in post-operative patients receiving opioids. Standard supportive therapy should be implemented.

Sandoz Opium & Belladonna should not be used in the early post-operative period (12 to 24 hours post-surgery) unless the patient is ambulatory and gastrointestinal function is normal.

Psychomotor Impairment

Sandoz Opium & Belladonna may impair the mental and/or physical abilities needed for certain potentially hazardous activities such as driving a car or operating machinery. Patients should be cautioned accordingly. Patients should also be cautioned about the combined effects of Opium and Belladonna suppository with other CNS depressants, including other opioids, phenothiazine, sedative/hypnotics and alcohol.

Respiratory

Respiratory Depression: Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression from opioid use, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status. Opium and Belladonna suppository should be used with extreme caution in patients with substantially decreased respiratory reserve, pre-existing respiratory depression, hypoxia ~~or~~ hypercapnia, kyphoscoliosis or severe obesity (see CONTRAINDICATIONS).

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of Sandoz Opium & Belladonna, the risk is greatest during the initiation of therapy or following a dose increase. Patients should be closely monitored for respiratory depression when initiating therapy with Sandoz Opium & Belladonna and following dose increases.

Life-threatening respiratory depression is more likely to occur in the elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients.

To reduce the risk of respiratory depression, proper dosing and titration of Sandoz Opium & Belladonna are essential. Overestimating the Sandoz Opium & Belladonna dose when converting patients from another opioid product can result in a fatal overdose with the first dose. In these patients, the use of non-opioid analgesics should be considered, if feasible (see WARNINGS AND PRECAUTIONS, Special Populations, Special Risk Groups, and DOSAGE AND ADMINISTRATION).

Use in Patients with Chronic Pulmonary Disease: Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression for respiratory depression, particularly when initiating therapy and titrating with opium, as in these patients, even usual therapeutic doses of Sandoz Opium & Belladonna may decrease respiratory drive to the point of apnea. In these patients, use of alternative non-opioid analgesics should be considered, if possible. The use of Sandoz Opium & Belladonna is contraindicated in patients with acute or severe bronchial asthma, chronic obstructive airway, or status asthmaticus (see CONTRAINDICATIONS). Further, systemically administered antimuscarinics such as belladonna should be used cautiously in debilitated patients with chronic pulmonary disease, since a reduction in bronchial secretions may lead to inspissation and formation of bronchial plugs.

Sexual Function/Reproduction

Long-term use of opioids may be associated with decreased sex hormone levels and symptoms such as low libido, erectile dysfunction, or infertility (see ADVERSE REACTIONS, Post-Market Adverse Drug Reactions).

Special Populations

Special Risk Groups: Opium and Belladonna suppository should be administered with caution to patients with a history of alcohol and drug abuse and in a reduced dosage to debilitated patients, and in patients with severely impaired pulmonary function, Addison's disease, hypothyroidism, myxedema, toxic psychosis, prostatic hypertrophy or urethral stricture.

Pregnant Women: Studies in humans have not been conducted. **Sandoz Opium & Belladonna** crosses the placental barrier and is not recommended to be administered to pregnant women unless, in the judgement of the physician, potential benefits outweigh the risks.

Prolonged maternal use of opioids during pregnancy can result in withdrawal signs in the neonate. Neonatal Opioid Withdrawal Syndrome (NOWS), unlike opioid withdrawal syndrome

in adults, may be life-threatening (see WARNINGS, PRECAUTIONS Neonatal Opioid Withdrawal Syndrome (NOWS), ADVERSE REACTIONS, Post-Marketing Experience).

Pregnant women using opioids should not discontinue their medication abruptly as this can cause pregnancy complication such as miscarriage or still-birth. Tapering should be slow and under medical supervision to avoid serious adverse events to the fetus.

Labour, Delivery and Nursing Women: Sandoz Opium and Belladonna is contraindicated in premature labour due to the belladonna. Since opioids can cross the placental barrier and are excreted in breast milk, Sandoz Opium & Belladonna is not recommended to be used in nursing women or during labour and delivery unless, in the judgement of the physician, the potential benefits outweigh the risks. Life-threatening respiratory depression can occur in the infant if opioids are administered to the mother. Naloxone, a drug that counters the effects of opioids, should be readily available if Sandoz Opium & Belladonna is used in this population.

Neonates should be observed closely for signs of respiratory depression if the mother has received opioid agonists during labour.

Pediatrics (< 18 years of age): The safety and efficacy of Opium preparations have not been studied in the pediatric population. Therefore, use of Sandoz Opium & Belladonna is not recommended in patients under 18 years of age.

Geriatrics (> 65 years of age): In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and titrate slowly, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see DOSAGE AND ADMINISTRATION and ACTION AND CLINICAL PHARMACOLOGY, Special Populations and Conditions, Geriatrics).

Patients with Renal and Hepatic Impairment:
Opioid agonists may have a prolonged duration and cumulative effect in patients with hepatic or renal dysfunction including those with hepatic precoma, jaundice, septic shock, ascites, or toxemia or eclampsia of pregnancy.

Antimuscarinics should also be used with caution in patients with hyperthyroidism, hepatic or renal disease, or hypertension (See DOSAGE AND ADMINISTRATION and ACTION AND CLINICAL PHARMACOLOGY sections).

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse effects of Sandoz Opium & Belladonna (suppository) are similar to those of other opioid analgesics, and represent an extension of pharmacological effects of the drug class. The major hazards of opioids include respiratory and central nervous system depression and to a lesser degree, circulatory depression, respiratory arrest, shock and cardiac arrest.

Opioid agonists may cause urinary retention and oliguria. Patients with prostatic hypertrophy or urethral stricture may be more prone to these effects.

Effects from belladonna
Naturally occurring alkaloids, such as belladonna, possess the full range of antimuscarinic and antinicotinic activities of atropine and thus have the potential for producing adverse central and peripheral effects associated with atropine. Adverse reactions frequently associated with the use of antimuscarinics include xerostomia (dry mouth), blurred vision, cycloplegia, mydriasis, photophobia, anhidrosis, urinary hesitancy and retention, tachycardia, palpitation, and constipation. These adverse effects may appear at therapeutic or subtherapeutic doses.

Other reported adverse effects of antimuscarinics include increased ocular tension (especially in patients with angle-closure glaucoma), loss of taste, headache, nervousness, drowsiness, weakness, dizziness, flushing, insomnia, nausea, vomiting and bloated feeling. Anaphylaxis, urticaria, rash that may progress to exfoliation, and various dermal manifestations have also been reported. Mental confusion and/or excitement may also occur, especially in geriatric patients.

Sedation: Sedation is a common side effect of opioid analgesics, especially in opioid naïve individuals. Sedation may also occur partly because patients often recuperate from prolonged fatigue after the relief of persistent pain. Most patients develop tolerance to the sedative effects of opioids within three to five days and, if the sedation is not severe, will not require any treatment except reassurance. If excessive sedation persists beyond a few days, the dose of the opioid should be reduced and alternate causes investigated. Some of these are: concurrent CNS depressant medication, hepatic or renal dysfunction, brain metastases, hypercalcemia and respiratory failure. If it is necessary to reduce the dose, it can be carefully increased again after three or four days if it is obvious that the pain is not being well controlled. Dizziness and unsteadiness may be caused by postural hypotension, particularly in elderly or debilitated patients, and may be alleviated if the patient lies down.

Nausea and Vomiting: Nausea is a common side effect on initiation of therapy with opioid analgesics and is thought to occur by activation of the chemoreceptor trigger zone, stimulation of the vestibular apparatus and through delayed gastric emptying. The prevalence of nausea declines following continued treatment with opioid analgesics. When instituting therapy with an opioid for chronic pain, the routine prescription of an antiemetic should be considered. In the cancer patient, investigation of nausea should include such causes as constipation, bowel obstruction, uremia, hypercalcemia, hepatomegaly, tumor invasion of celiac plexus and concurrent use of drugs with emetogenic properties. Persistent nausea which does not respond to dosage reduction may be caused by opioid-induced gastric stasis and may be accompanied by other symptoms including anorexia, early satiety, vomiting and abdominal fullness. These symptoms respond to chronic treatment with gastrointestinal prokinetic agents.

Constipation: Practically all patients become constipated while taking opioids on a persistent basis. In some patients, particularly the elderly or bedridden, fecal impaction may result. It is essential to caution the patients in this regard and to institute an appropriate regimen of bowel management at the start of prolonged opioid therapy. Stimulant laxatives, stool softeners, and other appropriate measures should be used as required. As fecal impaction may present as

overflow diarrhea, the presence of constipation should be excluded in patients on opioid therapy prior to initiating treatment for diarrhea.

Post-marketing Experience

Androgen deficiency: Chronic use of opioids may influence the hypothalamic-pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled for in studies conducted to date. Patients presenting with symptoms of androgen deficiency should undergo laboratory evaluation.

DRUG INTERACTIONS

Interaction with Benzodiazepines and Other Central Nervous System (CNS) Depressants (including alcohol): Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants (e.g. other opioids, sedatives/hypnotics, antidepressants, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, phenothiazines, neuroleptics, antihistamines, antiemetics, and alcohol) and beta-blockers, increases the risk of respiratory depression, profound sedation, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients closely for signs of respiratory depression and sedation (see WARNINGS AND PRECAUTIONS, Neurologic, Interactions with Central Nervous System Depressants (including benzodiazepines and alcohol) and Psychomotor Impairment). Sandoz Opium & Belladonna should not be consumed with alcohol as it may increase the chance of experiencing dangerous side effects.

Drug-Drug Interactions

Serotonergic Agents: Coadministration of Opium and Belladonna suppository with a serotonergic agent, such as a Selective Serotonin Re-uptake Inhibitor or a Serotonin Norepinephrine Re-uptake Inhibitor, may increase the risk of serotonin syndrome, a potentially life-threatening condition (see WARNINGS AND PRECAUTIONS, Neurologic).

Drug-Lifestyle Interactions

The concomitant use of alcohol should be avoided (see WARNINGS AND PRECAUTIONS, General).

DOSAGE AND ADMINISTRATION

Sandoz Opium & Belladonna should only be used in patients for whom alternative options are ineffective or not tolerated (e.g., non-opioid analgesics).

For acute pain, it is recommended that Sandoz Opium & Belladonna be used for a maximum of 7 days at the lowest dose that provides adequate pain relief.

All doses of opioids carry an inherent risk of fatal or non-fatal adverse events. This risk is increased with higher doses. The maximum recommended daily dose of Sandoz Opium & Belladonna is 4 suppositories (260 morphine milligram equivalent). Each patient should be assessed for their risk prior to prescribing Sandoz Opium & Belladonna, as the likelihood of experiencing serious adverse events can depend upon the type of opioid, duration of treatment, level of pain as well as the patient's own level of tolerance. In addition, the level of pain should be assessed routinely to confirm the most appropriate dose and the need for further use of Sandoz Opium & Belladonna (see D&A - Adjustment or reduction of Dosage).

Dosing Considerations

Sandoz Opium & Belladonna (suppositories) should be used with caution within 12 hours pre-operatively and within the first 12-24 hours post-operatively (see WARNINGS AND PRECAUTIONS, Peri-operative Considerations).

Rectal suppositories containing belladonna and opium should be moistened with water prior to insertion in the rectum. They should be placed against the rectal mucosa, in the lower anal canal. The drugs are not absorbed if pushed into a mass of stool.

Recommended Dose and Dosage Adjustment

Opium preparations should be given in the smallest effective dose and as infrequently as possible to minimize the development of tolerance and physical dependence. Reduced dosage is indicated in debilitated patients, in children and the elderly, and in patients receiving other CNS depressants.

Adults:

One suppository administered rectally every 6 hours as directed by a physician.

Children:

Safety and efficacy of suppositories containing powdered belladonna extract and powdered opium has not been established in children.

Opioid switching / rotation:

Conversion ratios for opioids are subject to variations in kinetics governed by genetics and other factors. Therefore, when switching from one opioid to another, **reduce calculated dose by 25-50%** to minimize the risk of overdose. Subsequently, up-titrate the dose as required to reach appropriate maintenance dose.

Geriatrics:

Respiratory depression has occurred in the elderly following administration of large initial doses of opioids to patients who were not opioid-tolerant or when opioids were co-administered with other agents that can depress respiration. Sandoz Opium & Belladonna should be initiated at a low dose and slowly titrated to effect (see WARNINGS AND PRECAUTIONS and ACTION AND CLINICAL PHARMACOLOGY).

Use with Non-Opioid Medications:
If a non-opioid analgesic is being provided, it may be continued. If the non-opioid is discontinued, consideration should be given to increasing the opioid dose to compensate for the non-opioid analgesic. **Sandoz Opium & Belladonna** can be safely used concomitantly with usual doses of other non-opioid analgesics.

Dosage adjustments should be based on the patient's clinical response.

Adjustment or Reduction of Dosage: Physical dependence with or without psychological dependence tends to occur with chronic administration of opioids, including **Sandoz Opium & Belladonna**. Withdrawal (abstinence) symptoms may occur following abrupt discontinuation of therapy. These symptoms may include body aches, diarrhea, gooseflesh, loss of appetite, nausea, nervousness or restlessness, runny nose, sneezing, tremors or shivering, stomach cramps, tachycardia, trouble with sleeping, unusual increase in sweating, palpitations, unexplained fever, weakness and yawning.

Following successful relief of moderate to severe pain, periodic attempts to reduce the opioid dose should be made. Smaller doses or complete discontinuation may become feasible due to a change in the patient's condition or mental state. Patients on prolonged therapy should be withdrawn gradually from the drug if it is no longer required for pain control. In patients who are appropriately treated with opioid analgesics and who undergo gradual withdrawal for the drug, these symptoms are usually mild (see WARNINGS and PRECAUTIONS). Tapering should be individualized and carried out under medical supervision.

Patient should be informed that reducing and/or discontinuing opioids decreases their tolerance to these drugs. If treatment needs to be re-initiated, the patient must start at the lowest dose and titrate up to avoid overdose.

Disposal
Sandoz Opium & Belladonna should be kept in a safe place, out of the sight and reach of children before, during and after use. Sandoz Opium & Belladonna should not be used in front of children, since they may copy these actions.

Sandoz Opium & Belladonna should never be disposed of in household trash. Disposal via a pharmacy take back program is recommended. Unused or expired Sandoz Opium & Belladonna should be properly disposed of as soon as it is no longer needed to prevent accidental exposure to others, including children or pets. If temporary storage is required before disposal, a sealed child-proof container, such as a biohazard waste container or a lockable medication box could be obtained from a pharmacy.

Missed Dose
If the patient forgets to take one or more doses, they should take their next dose at the next scheduled time and in the normal amount.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Opium has analgesic and opioid actions that is due mainly to its content of morphine. It acts less rapidly than morphine since opium appears to be more slowly absorbed. Following rectal administration, opium in suppository form has an onset of action of 15-30 minutes and analgesia is maintained for 3-5 hours. Like the other opioid agonists, opium preparations are metabolized in the liver. The relaxing action of the papaverine and noscapine on intestinal muscle makes it more constipating than morphine.

Belladonna is a naturally occurring mixture of tertiary amine alkaloids of the antimuscarinic class.

Central Nervous System:
Opium and Belladonna suppository produces respiratory depression by direct action on brain stem respiratory centres. The respiratory depression involves both a reduction in the responsiveness of the brain stem centres to increases in CO_2 tension and to electrical stimulation.

Opium and Belladonna suppository depresses the cough reflex by direct effect on the cough centre in the medulla. Antitussive effects may occur with doses lower than those usually required for analgesia.

Opium and Belladonna suppository causes miosis, even in total darkness. Pinpoint pupils are a sign of opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origin may produce similar findings). Marked mydriasis rather than miosis may be seen with hypoxia in the setting of oxycodone overdose.

Gastrointestinal Tract and Other Smooth Muscle:
Opium and Belladonna suppository causes a reduction in motility associated with an increase in smooth muscle tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone may be increased to the point of spasm resulting in constipation. Other opioid-induced effects may include a reduction in gastric, biliary and pancreatic secretions, spasm of the sphincter of Oddi, and transient elevations in serum amylase.

Cardiovascular System:
Opium and Belladonna suppository may produce release of histamine with or without associated peripheral vasodilation. Manifestations of histamine release and/or peripheral vasodilatation may include pruritus, flushing, red eyes, hyperhidrosis and/or orthostatic hypotension.

Endocrine System:

Opioids may influence the hypothalamic-pituitary-adrenal or -gonadal axes. Some changes that can be seen include an increase in serum prolactin, and decreases in plasma cortisol and testosterone. Clinical signs and symptoms may be manifest from these hormonal changes.

Immune System:
In vitro and animal studies indicate that opioids have a variety of effects on immune functions, depending on the context in which they are used. The clinical significance of these findings is unknown.

Special Populations and Conditions

Pediatrics: Individuals under 18 years of age should not take Sandoz Opium & Belladonna suppository /other formulations.

STORAGE AND STABILITY

Store Sandoz Opium & Belladonna between 15 and 30 ºC

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each white, cone-shaped Sandoz Opium & Belladonna suppository contains: 65 mg of powdered opium and 15 mg of dry extract of belladonna. The non-medicinal ingredients are … Tartrazine-free. Boxes of 12.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

[N] SANDOZ OPIUM & BELLADONNA®
(Opium and Belladonna Suppository)

Read this carefully before you start taking **Sandoz Opium & Belladonna** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Sandoz Opium & Belladonna**.

Serious Warnings and Precautions

- **Even if you take Sandoz Opium & Belladonna as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.** To understand your risk of opioid addiction, abuse, and misuse you should speak to your prescriber (e.g., doctor).
- **Sandoz Opium and Belladonna suppositories must be inserted whole, not crushed or cut, and should not be chewed. This can be dangerous and can lead to death or seriously harm you.**
- **You may get life-threatening breathing problems while taking Sandoz Opium & Belladonna. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your Sandoz Opium & Belladonna. They could die from taking it. If a person has not been prescribed Sandoz Opium & Belladonna, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took Sandoz Opium & Belladonna while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:**
  - **has changes in their breathing (such as weak, difficult or fast breathing)**
  - **is unusually difficult to comfort**
  - **has tremors (shakiness)**
  - **has increased stools, sneezing, yawning, vomiting, or fever**

  Seek immediate medical help for your baby.
- **Taking Sandoz Opium & Belladonna with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause**

severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is Sandoz Opium & Belladonna used for?

Sandoz Opium & Belladonna is used for the relief of moderate to severe pain from bladder spasms, that is not helped by non-opioid medications, such as ibuprofen and acetaminophen.

How does Sandoz Opium & Belladonna work?

Sandoz Opium & Belladonna is a combination preparations containing powdered opium and belladonna extract in rectal suppository form. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

What are the ingredients in Sandoz Opium & Belladonna?

Medicinal ingredient: powdered opium and belladonna extract
Non-medicinal ingredients: Lactose anhydrous and Covi-Ox T70 (mixed Tocopherol)

Sandoz Opium & Belladonna comes in the following dosage forms:
Suppository

Do not use Sandoz Opium & Belladonna if:

- your doctor did not prescribe it for you
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- you have severe asthma, trouble breathing, or other breathing problems
- you have any heart problems
- you have bowel blockage or narrowing of the stomach or intestines
- you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you have a brain tumor
- you suffer from alcoholism
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOI) (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline)
- you are going to have, or recently had, a planned surgery

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Opium & Belladonna. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse
- have severe kidney, liver or lung disease

- have heart disease
- have low blood pressure
- have past or current depression
- suffer from chronic or severe constipation
- have problems with your adrenal or prostate gland
- have, or had in the past, hallucinations or other severe mental problems
- suffer from migraines
- are pregnant or planning to become pregnant,

Other warnings you should know about:

Opioid dependence and addiction: There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

Pregnancy, nursing, labour and delivery:

Do not use Sandoz Opium & Belladonna while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. Sandoz Opium & Belladonna can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking Sandoz Opium & Belladonna, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your doctor will monitor and guide you on how to slowly stop taking Sandoz Opium & Belladonna. This may help avoid serious harm to your unborn baby.

Disorder of the adrenal gland: You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off Sandoz Opium & Belladonna.

Serotonin Syndrome: Sandoz Opium & Belladonna can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take Sandoz Opium & Belladonna with certain anti-depressants or migraine medications.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;

- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to **Sandoz Opium & Belladonna**. The suppositories can cause:

- drowsiness
- dizziness or
- light headedness

This can usually occur after you take your first dose and when your dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Sandoz Opium & Belladonna:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol.
  Do not drink alcohol while you are taking **Sandoz Opium & Belladonna**. It can lead to:
  - drowsiness
  - unusually slow or weak breathing
  - serious side effects or
  - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by Sandoz Opium & Belladonna
- other opioid analgesics (drugs used to treat pain)
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take **Sandoz Opium & Belladonna** with MAO inhibitors (MAOI) or if you have taken MAOI's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin (such as coumadin) and other anticoagulants (used for prevention or treatment of blood clots)
- anti-retroviral drugs (used to treat viral infections)
- anti-fungal drugs (used to treat fungal infections)

- antibiotic drugs (used to treat bacterial infections)
- some heart medications (such as beta blockers)
- drugs used to treat migraines (e.g. triptans)
- grapefruit juice
- St. John's Wort

How to take Sandoz Opium & Belladonna:

Place the **Sandoz Opium & Belladonna** suppository just inside your rectum, past the ring of muscle that closes your anus. The medicine will not be absorbed if the suppository is pushed into a mass of stool.

Usual Adult Starting Dose:

Your dose is tailored/personalized just for you. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor.

Your doctor will prescribe the lowest dose that works to control your pain. It is recommended that you only take Sandoz Opium & Belladonna for up to 7 days. If you need to take Sandoz Opium & Belladonna for longer, your doctor will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose. Review your pain regularly with your doctor to determine if you still need **Sandoz Opium & Belladonna**. Be sure to use **Sandoz Opium & Belladonna** only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking **Sandoz Opium & Belladonna**, tell your doctor immediately.

Stopping your Medication

If you have been taking **Sandoz Opium & Belladonna** for more than a few days you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking Sandoz Opium & Belladonna. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)

- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking Sandoz Opium & Belladonna.

Refilling your Prescription for Sandoz Opium & Belladonna:

A new written prescription is required from your doctor each time you need more **Sandoz Opium & Belladonna**. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

If you think you have taken too much **Sandoz Opium & Belladonna**, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

Missed Dose:

If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once. If you miss several doses in a row, talk to your doctor before restarting your medication.

What are possible side effects from using Sandoz Opium & Belladonna?

These are not all the possible side effects you may feel when taking **Sandoz Opium & Belladonna**. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Insomnia
- Dizziness
- Fainting
- Nausea, vomiting, or a poor appetite
- Dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching
- Light headedness
- Sweating
- Constipation
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using **Sandoz Opium & Belladonna.**

Serious side effects and what to do about them				
Symptom / effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
RARE	**Overdose:** hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			√
	Respiratory Depression: slow, shallow or weak breathing.			√
	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
	Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			√
	Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		√	
	Fast, Slow or Irregular Heartbeat: heart palpitations.		√	

	Low Blood Pressure: dizziness, fainting, light-headedness.	√		
	Serotonin Syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.
3 ways to report:

- Online at MedEffect: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html).

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep unused or expired Sandoz Opium & Belladonna in a secure place to prevent theft, misuse or accidental exposure.**
- Store between 15 and 30 ºC.
- **Keep Sandoz Opium & Belladonna under lock, out of sight and reach of children and pets.**
- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes B Sandoz Opium & Belladonna, get emergency help right away.**

Disposal:

Sandoz Opium & Belladonna should never be thrown into household trash, where children

and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about Sandoz Opium & Belladonna:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals and includes this consumer medication information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); Sandoz Canada Inc. website http://www.sandoz.ca, or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

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