Belladonna and Opium Suppositories C-II

16.2 mg/30 mg / 16.2 mg/60 mg

Belladonna and Opium Suppositories C-II are indicated for the management of ureteral spasm pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[1]

Discover more at belladonna-opium.com

Padagis®

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction, Abuse, and Misuse - Belladonna and opium suppositories expose users to risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing and monitor regularly for the development of these conditions.

Life-Threatening Respiratory Depression - Serious, life-threatening, or fatal respiratory depression may occur with use. Monitor for respiratory depression, especially during initiation or following a dose increase.

Accidental Exposure - Accidental exposure of even one dose, especially by children, can result in a fatal overdose of opium.

Neonatal Opioid Withdrawal Syndrome - Prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management.

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.

- **Reserve concomitant prescribing with 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.**

Please see Boxed WARNING and safety information in the full prescribing information at belladonna-opium.com.

Why Belladonna and Opium Suppositories

Belladonna and Opium Suppositories C-II are an opioid agonist indicated for the management of **ureteral spasm pain** severe enough to require an opioid analgesic when alternative treatments are inadequate.[1]

Belladonna and Opium Suppositories are available in two strengths:

- **Belladonna 16.2 mg and opium 30 mg C-II**
- **Belladonna 16.2 mg and opium 60 mg C-II**

Your Patients Have Questions

Below are some questions your patients may ask about Belladonna and Opium Suppositories. For details, please review the full prescribing information at belladonna-opium.com.

How do Belladonna and Opium Suppositories work?

Belladonna and Opium Suppositories work by relaxing the bladder muscles, reducing spasms and blocking pain signals in the brain.[2] This medication combines an antispasmodic agent (belladonna) and a narcotic analgesic (opium),[1] making it a unique treatment option for adult patients experiencing severe ureteral spasm pain.

How long will patients need to take Belladonna and Opium Suppositories?

It is important to prescribe the lowest effective dosage for the shortest duration necessary, based on your adult patient's individual factors such as pain severity, response to treatment, prior analgesic experience and risk factors for addiction, abuse and misuse.[1]

What are the possible adverse reactions of Belladonna and Opium Suppositories?

Patients should be advised of these possible adverse reactions: drowsiness, dry mouth, urinary retention, photophobia, rapid pulse, dizziness and blurred vision, constipation, nausea and vomiting.[1]
The possibility of adverse reactions should be explained to patients before starting therapy. Please see full prescribing information for a comprehensive list of Belladonna and Opium Suppository side effects.

What should patients know about addiction, abuse or misuse of Belladonna and Opium Suppositories?

It's essential to advise patients that Belladonna and Opium Suppositories contain opium, a Schedule II controlled substance with potential for addiction, abuse and misuse.[1] While the risk of addiction in any individual is unknown, it can occur at recommended dosages and if misused or abused.[1] Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended.[1]

When prescribing Belladonna and Opium Suppositories, what should I tell patients and caregivers about naloxone and opioid overdose?

Discuss the availability of naloxone for the emergency treatment of opioid overdose with both patient and caregivers.[1] Inform them about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines.[1]

Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of calling 911 or getting emergency medical help, even if naloxone is administered.[1] Consider prescribing naloxone, based on the patient's risk factors for overdose, such as concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose or if the patient has household members (including children) other close contacts at risk for accidental ingestion or overdose.[1]

Who should not be prescribed Belladonna and Opium Suppositories?

Patients should not use Belladonna and Opium Suppositories if they have hypersensitivity to opium or belladonna.[1] These suppositories are contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days, known or suspected gastrointestinal obstruction, including paralytic ileus.[1] These preparations are not recommended for use in children.[1]

References

[1] Belladonna and Opium [prescribing information]. Allegan, MI: Padagis US LLC., 2025

[2] Belladonna; Opium Rectal Suppositories. Cleveland Clinic website. Available at https://my.clevelandclinic.org/health/drugs/20372-belladonna-opium-rectal-suppositories. Accessed Jan. 20, 2025.

Belladonna and Opium Suppositories Important Safety Information

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

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Accidental Exposure - Accidental exposure of even one dose, especially by children, can result in a fatal overdose of opium.

Neonatal Opioid Withdrawal Syndrome - Prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management.

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.

- **Reserve concomitant prescribing with 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.**

CONTRAINDICATIONS

Belladonna and opium suppositories are contraindicated in patients with:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity to opium or belladonna
- Glaucoma
- Severe hepatic or renal disease
- Narcotic idiosyncrasies
- Convulsive disorders
- Acute alcoholism
- Delirium tremens
- Premature labor

WARNINGS AND PRECAUTIONS

In addition to Boxed WARNINGS,

Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients

Patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive including apnea.

Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients. Monitor such patients closely, particularly when initiating and titrating belladonna and opium and when given with other drugs that depress respiration.

Interactions with Monoamine Oxidase Inhibitors

MAOIs may potentiate the effects of opioids, including respiratory depression, coma, and confusion.

Adrenal Insufficiency

Adrenal insufficiency has been reported with opioid use, more often following >1 month of use.

Severe Hypotension

Severe hypotension including orthostatic hypotension and syncope may occur. There is increased risk in patients with reduced blood volume or concurrent administration of certain CNS depressant drugs. Monitor these patients for signs of hypotension after initiating or titrating. Avoid the use of belladonna and opium suppositories in patients with circulatory shock as it may cause vasodilation that can further reduce cardiac output and blood pressure.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness

In patients who may be susceptible to the intracranial effects of CO_2 retention, belladonna and opium suppositories may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy.

Opioids may obscure the clinical course in a patient with a head injury. Avoid use in patients with impaired consciousness or coma.

Risks of Use in Patients with Gastrointestinal Conditions

The opium in belladonna and opium suppositories may cause spasm of the sphincter of Oddi. Opioids may increase serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

Increased Risk of Seizures in Patients with Seizure Disorders

The opium in belladonna and opium suppositories may increase the frequency of seizures in patients with seizure disorders, and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during therapy.

Withdrawal

Do not abruptly discontinue in a patient physically dependent on opioids. Rapid tapering of opium in a patient physically dependent on opioids may lead to a withdrawal syndrome and return of.

Additionally, avoid the use of mixed agonist/antagonist (e.g., pentazocine, nalbuphine, and butorphanol) or partial agonist (e.g., buprenorphine) analgesics in patients who are receiving a full opioid agonist analgesic, including belladonna and opium suppositories as it may reduce the analgesic effect and/or precipitate withdrawal symptoms.

Risks of Driving and Operating Machinery

Mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery may be impaired with use.

ADVERSE REACTIONS

Belladonna may cause drowsiness, dry mouth, urinary retention, photophobia, rapid pulse, dizziness and blurred vision. Opium usage may result in constipation, nausea or vomiting. Pruritis and urticaria may occasionally occur. Hypersensitivity to opium or belladonna may occur.

USE IN SPECIFIC POPULATIONS

Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome.

Chronic use of opioids may cause reduced fertility in females and males of reproductive potential.

INDICATION FOR USE

Belladonna and opium suppositories are indicated for the management of ureteral spasm pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses reserve belladonna and opium suppositories for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]:

- Have not been tolerated, or are not expected to be tolerated,
- Have not provided adequate analgesia, or are not expected to provide adequate analgesia

For additional safety information about Belladonna and Opium Suppositories, click here for the Full Prescribing Information.

You are encouraged to report negative side effects of prescription drugs to Padagis® at 866-634-9120 or the FDA at www.fda.gov/medwatch, or call 1-800-FDA-1088.

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Visit www.belladonna-opium.com for more information.

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