Medication Guide Belladonna (bell ah DON ah) and Opium (OH pee um) Suppositories. CII

Belladonna and opium suppositories are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage ureteral spasm pain severe enough to require an opioid
 analgesic, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about belladonna and opium suppositories:

- **Get emergency help or call 911 right away if you take too much belladonna and opium suppositories (overdose).** When you first start taking belladonna and opium suppositories, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking belladonna and opium suppositories 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.
- Never give anyone else your belladonna and opium suppositories. They could die from taking them. Selling or giving away belladonna and opium suppositories is against the law.
- Store belladonna and opium suppositories securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take belladonna and opium suppositories if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking belladonna and opium suppositories, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of belladonna and opium suppositories during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- breastfeeding. Opium passes into breastmilk and may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking belladonna and opium suppositories with certain other
 medicines can cause serious side effects that could lead to death.

When taking belladonna and opium suppositories:

- Do not change your dose. Take belladonna and opium suppositories exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Do not take more than your prescribed dose. If you miss a dose, consult with your healthcare provider.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking belladonna and opium suppositories regularly, do not stop taking belladonna and opium suppositories without talking to your healthcare provider.
- After you stop taking belladonna and opium suppositories, return unused suppositories to the pharmacy or deliver to an accredited disposal site. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.
- Unwrap suppository, then moisten finger and suppository with water before inserting.

While taking belladonna and opium suppositories DO NOT:

- Drive or operate heavy machinery, until you know how belladonna and opium suppositories affects you. Belladonna and opium suppositories can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with belladonna and opium suppositories may cause you to overdose and die.

The possible side effects of belladonna and opium suppositories:

 Constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

• Trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of belladonna and opium suppositories. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov



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