Belladonna and Opium

Warning

- This drug may be habit-forming with long-term use.
- This drug is a strong pain drug that can put you at risk for addiction, abuse, and misuse. Misuse or abuse of this drug can lead to overdose and death. Talk with your doctor.
- You will be watched closely to make sure you do not misuse, abuse, or become addicted to this drug.
- This drug may cause very bad and sometimes deadly breathing problems. Call your doctor right away if you have slow, shallow, or trouble breathing.
- The chance of very bad and sometimes deadly breathing problems may be greater when you first start this drug or anytime your dose is raised.
- Even one dose of this drug may be deadly if it is taken by someone else or by accident, especially in children. If this drug is taken by someone else or by accident, get medical help right away.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Using this drug for a long time during pregnancy may lead to withdrawal in the newborn baby. This can be life-threatening. Talk with the doctor.
- This drug has an opioid drug in it. The use of opioid drugs along with a benzodiazepine drug or other drugs that may make you drowsy or slow your actions has led to very bad side effects. Side effects that have happened include slowed or trouble breathing and deaths. Benzodiazepine drugs include drugs like alprazolam, diazepam, and lorazepam. Benzodiazepine drugs are used to treat many health problems like anxiety, trouble sleeping, or seizures. Talk with the doctor.
- Many drugs interact with this drug and can raise the chance of side effects.
like deadly breathing problems. Talk with your doctor and pharmacist to make sure it is safe to use this drug with all of your drugs.

- Do not take with alcohol or products that have alcohol. Unsafe and sometimes deadly effects may happen.
- Get medical help right away if you feel very sleepy, very dizzy, or if you pass out. Caregivers or others need to get medical help right away if the patient does not respond, does not answer or react like normal, or will not wake up.

**What is this drug used for?**

- It is used to ease pain.

**What do I need to tell my doctor BEFORE I take this drug?**

**For all patients taking this drug:**

- If you have an allergy to atropine, belladonna, morphine, opium, or any other part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you have any of these health problems: Bad reactions to opioid drugs, early labor, glaucoma, kidney disease, liver disease, or seizures.
- If you have any of these health problems: Lung or breathing problems like asthma, trouble breathing, or sleep apnea; high levels of carbon dioxide in the blood; or stomach or bowel block or narrowing.
- If you are going through alcohol withdrawal.
- If you have recently drunk a lot of alcohol.
- If you have taken certain drugs used for low mood (depression) like isocarboxazid, phenelzine, or tranylcypromine or drugs used for Parkinson’s disease like selegiline or rasagiline in the last 14 days. Taking this drug within 14 days of those drugs can cause very bad high blood pressure.
- If you are taking any of these drugs: Linezolid or methylene blue.
• If you are taking any of these drugs: Buprenorphine, butorphanol, nalbuphine, or pentazocine.

Children:

• If your child is younger than 12 years of age. Do not give this drug to a child younger than 12 years of age.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

• Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.

• Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.

• To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.

• Do not use more than what your doctor told you to use. Do not use more often or longer than what you were told. Doing any of these things may raise the chance of very bad side effects.

• If you have been taking this drug on a regular basis and you stop it all of a sudden, you may have signs of withdrawal. Do not stop taking this drug all of a sudden without calling your doctor. Tell your doctor if you have any bad effects.

• If you have been taking this drug for a long time or at high doses, it may not work as well and you may need higher doses to get the same effect. This is known as tolerance. Call your doctor if this drug stops working well. Do not take more than ordered.
• This drug may raise the chance of seizures in some people, including people who have had seizures in the past. Talk to your doctor to see if you have a greater chance of seizures while taking this drug.

• Bright lights may bother you. Wear sunglasses.

• Do not take this drug with other strong pain drugs or if you are using a pain patch without talking to your doctor first.

• If you are 65 or older, use this drug with care. You could have more side effects.

• This drug may cause harm to the unborn baby if you take it while you are pregnant. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.

• Tell your doctor if you are breast-feeding or plan to breast-feed. This drug passes into breast milk and may harm your baby.

What are some side effects that I need to call my doctor about right away?

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

• Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

• Trouble breathing, slow breathing, or shallow breathing.

• Very bad dizziness or passing out.

• Very bad belly pain.

• Very bad constipation.

• Seizures.

• Chest pain or pressure or a fast heartbeat.

• Feeling very sleepy.
• Feeling confused.
• Trouble passing urine.
• Blurred eyesight.
• If bright lights bother your eyes.

• A very bad and sometimes deadly health problem called serotonin syndrome may happen if you take this drug with drugs for depression, migraines, or certain other drugs. Call your doctor right away if you have agitation; change in balance; confusion; hallucinations; fever; fast or abnormal heartbeat; flushing; muscle twitching or stiffness; seizures; shivering or shaking; sweating a lot; very bad diarrhea, upset stomach, or throwing up; or very bad headache.

• Taking an opioid drug like this drug may lead to a rare but very bad adrenal gland problem. Call your doctor right away if you have very bad dizziness or passing out, very bad upset stomach or throwing up, or if you feel less hungry, very tired, or very weak.

• Long-term use of an opioid drug like this drug may lead to lower sex hormone levels. This may lead to signs like change in sex ability in men, no menstrual period in women, lowered interest in sex, or fertility problems. Call your doctor if you have any of these signs.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

• Dizziness.
• Feeling sleepy.
• Dry mouth.
• Constipation.
• Upset stomach or throwing up.
• Feeling tired or weak.
• Headache.
• Belly pain.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

**How is this drug best taken?**

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

• Use suppository rectally.

• To use, take off foil wrapper and wet suppository with cold water. Use your finger to push the suppository well up into the rectum.

**What do I do if I miss a dose?**

• If you use this drug on a regular basis, use a missed dose as soon as you think about it.

• If it is close to the time for your next dose, skip the missed dose and go back to your normal time.

• Do not use 2 doses or extra doses.

• Many times this drug is used on an as needed basis. Do not use more often than told by the doctor.

**How do I store and/or throw out this drug?**

• Store at room temperature. Do not refrigerate or freeze.

• Store in a dry place. Do not store in a bathroom.

• Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.

• Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.
General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.

- Do not share your drugs with others and do not take anyone else’s drugs.

- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.

- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.

- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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