Warning

- This drug is a strong pain drug that can put your child at risk for addiction, abuse, and misuse. Misuse or abuse of this drug can lead to overdose and death. Talk with your child’s doctor.

If your child is pregnant:

- 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.

What is this drug used for?

- It is used to ease pain.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child has an allergy to this drug or any part of this drug.
- If your child is allergic to any drugs like this one or any other drugs, foods, or other substances. Tell the doctor about the allergy and what signs your child had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If your child has any of these health problems: Asthma, drinks alcohol, early labor, glaucoma, kidney disease, liver disease, lung disease, or seizures.

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

Tell the doctor and pharmacist about all of your child’s drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for your child to take this drug with all of his/her drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking
What are some things I need to know or do while my child takes this drug?

- Tell all of your child’s health care providers that your child is taking this drug. This includes your child’s doctors, nurses, pharmacists, and dentists.
- This drug may be habit-forming with long-term use.
- If your child has been taking this drug on a regular basis and stops taking it all of a sudden, your child may have signs of withdrawal. Do not stop giving this drug all of a sudden without calling the doctor. Tell the doctor if your child has any bad effects.
- Have your child avoid tasks or actions that call for alertness until you see how this drug affects your child. These are things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles.
- To lower the chance of feeling dizzy or passing out, have your child rise slowly if your child has been sitting or lying down. Have your child be careful going up and down stairs.
- Talk with the doctor before giving your child other drugs and natural products that may slow your child’s actions.
- Alcohol may interact with this drug. Be sure your child does not drink alcohol.
- Bright lights may bother your child. Have your child wear sunglasses.
- Do not give this drug with other strong pain drugs or pain patches without talking to your child’s doctor first.
- Do not give to a child younger than 12 years of age.

If your child is pregnant or breast-feeding a baby:

- Talk with the doctor if your child is pregnant, becomes pregnant, or is breast-feeding a baby. You will need to talk about the benefits and risks of using this drug.

What are some side effects that I need to call my doctor.
child’s 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 child’s doctor or get medical help right away if your child has 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.
- Very bad dizziness or passing out.
- Feeling confused.
- A fast heartbeat.
- Change in eyesight.
- Not able to pass urine or change in how much urine is passed.
- If bright lights bother your child’s eyes.
- A very bad and sometimes deadly health problem called serotonin syndrome may happen if your child takes this drug with drugs for depression, migraines, or certain other drugs. Call the doctor right away if your child has 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 pain drug like this drug may lead to a rare but very bad adrenal gland problem. Call your child’s doctor right away if your child has very bad dizziness or passing out, very bad upset stomach or throwing up, or if your child feels 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 males, no menstrual period in females, lowered interest in sex, or fertility problems. If any of these apply to your child, call your child’s doctor.

**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 child’s doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

- Dizziness.
- Feeling sleepy.
- Dry mouth.
- Upset stomach or throwing up.
- Hard stools (constipation).

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

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child’s 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. Have your child lie down on his/her side. Use your finger to push the suppository well up into the rectum.

What do I do if my child misses a dose?

- If your child uses this drug on a regular basis, give a missed dose as soon as you think about it.
- If it is close to the time for your child’s next dose, skip the missed dose and go back to your child’s normal time.
- Do not give 2 doses at the same time or extra doses.
- Many times this drug is given on an as needed basis. Do not give to your child more often than told by the doctor.

How do I store and/or throw out this drug?
• Store at room temperature.
• 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 child’s symptoms or health problems do not get better or if they become worse, call your child’s doctor.
• Do not share your child’s drug with others and do not give anyone else’s drug to your child.
• Keep a list of all your child’s drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your child’s doctor.
• Talk with your child’s doctor before giving your child 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 child’s 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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If you have any questions or concerns, talk with a member of your healthcare team. You can reach them Monday through Friday from 9:00 AM to 5:00 PM at __________________. After 5:00 PM, during the weekend, and on holidays, please call________________________. If there’s no number listed, or you’re not sure, call 212-639-2000.

Belladonna and Opium

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