What is this drug used for?

- It is used to treat sleep problems.

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

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has any of these health problems: Falling asleep when not expected to (narcolepsy) or liver problems.
- If your child is taking any of these drugs: Another drug to help with sleep, boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, nefazodone, neflinavir, posaconazole, ritonavir, saquinavir, telaprevir, or telithromycin.

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 to give this drug with all of your child’s other drugs and health problems. Do not start, stop, or change the dose of any drug your child takes without checking with the doctor.

**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.

- Have your child avoid tasks or actions that call for alertness for at least 8 hours after taking this drug. These include things like riding a bike, playing sports, or using items such as scissors, lawnmowers, electric scooters, toy cars, or motorized vehicles. Have your child avoid these tasks or actions until your child feels fully awake.

- Your child may still feel sleepy the day after taking this drug. If your child drives, this can affect driving and may raise the chance of falling asleep while driving. Call the doctor right away if your child drives and feels sleepy during the day.

- This drug may be habit-forming with long-term use.

- When sleep drugs are used nightly for more than a few weeks, they may not work as well to help your child sleep. This is known as tolerance. Only give your child sleep drugs for a short time. If your child’s sleep problems last, call the doctor.

- Alcohol may interact with this drug. Be sure your child does not drink alcohol.

- Talk with your child’s doctor before your child uses marijuana, other forms of cannabis, or prescription or OTC drugs that may slow your child’s actions.

- Some people have done certain tasks or actions while they were not fully awake like driving, and making and eating food. Most of the time, people...
do not remember doing these things. Tell the doctor if this happens to your child.

- If your child drinks grapefruit juice or eats grapefruit often, talk with your child’s doctor.

- This drug may make your child feel sleepy and less alert. This may lead to falling. If you have questions, talk with your child’s doctor.

- If your child is overweight, talk with the doctor.

- If your child is a female, give this drug with care. She could have more side effects.

**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 to your child and the baby.

**What are some side effects that I need to call my 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.

- New or worse behavior or mood changes like depression or thoughts of suicide.

- Feeling confused.

- Hallucinations (seeing or hearing things that are not there).

- Memory problems or loss.

- Not able to move or speak for up to several minutes while going to sleep
or waking up.

- Muscle weakness can happen with this drug. This can last from seconds to a few minutes and can happen both at night and during the day. Call the doctor right away if this happens to your child.

**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:

- Feeling sleepy the next day.
- Headache.

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.

- Give within 30 minutes of bedtime.
- Give with or without food. If given with or right after a meal, this drug may take longer to work.
- If your child still has trouble sleeping after 7 to 10 days, call your child’s doctor.
- Do not give this drug unless your child can get a full night’s sleep (at least 7 to 8 hours) before needing to be active again.
What do I do if my child misses a dose?

- If your child takes this drug on a regular basis, give a missed dose as soon as you think about it.
- If your child will not be able to get a full night’s sleep (at least 7 hours) after taking the missed dose, skip the missed dose and go back to your child’s normal time.
- Do not give more than 1 dose of this drug in the same day.
- 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 in a dry place. Do not store in a bathroom.
- Store in the original container to protect from light.
- 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.
- 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
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