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Zolpidem: Patient drug information

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(For additional information see "Zolpidem: Drug information" and see "Zolpidem: Pediatric drug information")

Brand Names: US

Ambien; Ambien CR; Edluar; Intermezzo; Zolpimist

Brand Names: Canada

APO-Zolpidem ODT; PMS-Zolpidem ODT; Sublinox

Warning

• Some people taking this drug have done things like sleepwalking, sleep driving, making and eating food, having sex, or other actions while not fully awake. Rarely, this has led to severe injuries or death. Most of the time people do not remember doing these things. If this happens, stop taking this drug and tell your doctor right away.

What is this drug used for?

• It is used to treat sleep problems.

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

• If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

- If you have liver disease.
- If you are taking any drugs or natural products used for sleep. There are many products used for sleep. Ask your doctor or pharmacist if you are not sure.
- If you have taken this drug or a drug like this one in the past and have done any tasks or actions while not fully awake.
- If you are taking any of these drugs: Rifampin or St. John's wort.

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?

All products:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- When sleep drugs are used nightly for more than a few weeks, they may not work as well to help sleep problems. This is known as tolerance. Only use sleep drugs for a short time. If sleep problems last, call the doctor.
- Long-term or regular use of this drug may lead to dependence. Stopping this drug all of a sudden may lead to signs of withdrawal. Talk to your doctor before you lower the dose or stop this drug. You will need to follow your doctor's instructions. Tell your doctor if you have any bad effects.
- Do not take naps.
- 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.
- Avoid alcohol while taking this drug. Do not take this drug if you drank alcohol that evening or before bed.
- Talk with your doctor before you use marijuana, other forms of cannabis, or prescription or OTC drugs that may slow your actions.
- If you have phenylketonuria (PKU), talk with your doctor. Some products have phenylalanine.

- This drug may cause sleepiness or lower alertness. This may lead to falls and injuries that may be very bad. Very bad injuries like broken hips and bleeding in the brain have happened. Talk with the doctor.
- If you are a woman, use this drug with care. You could have more side effects.
- If you are 60 or older, use this drug with care. You could have more side effects.
- This drug is not approved for use in children. The chance of side effects like dizziness and hallucinations may be raised in children. However, your child's doctor may decide the benefits of taking this drug may outweigh the risks. Talk with the doctor if you have questions about giving this drug to your child.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.
- Taking this drug in the third trimester of pregnancy may lead to some health problems in the newborn. Talk with the doctor.

Extended-release tablets:

• You may not be alert. Do not drive or do other tasks or actions that call for you to be alert on the day after you take this drug.

All other products:

• Avoid driving and doing other tasks or actions that call for you to be alert after you take this drug. You may still feel sleepy the day after you take this drug. Avoid these tasks or actions until you feel fully awake.

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.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Hallucinations (seeing or hearing things that are not there).
- Feeling confused.

- Not thinking clearly.
- Trouble breathing, slow breathing, or shallow breathing.
- Change in balance.
- Change in eyesight.
- Memory problems or loss.
- A very bad reaction called angioedema has happened with this drug. Sometimes, this may be life-threatening. Signs may include swelling of the hands, face, lips, eyes, tongue, or throat; trouble breathing; trouble swallowing; or unusual hoarseness. Get medical help right away 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:

- Feeling dizzy, tired, or weak.
- Feeling sleepy the next day.
- Headache.
- Upset stomach.
- Diarrhea.

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.

All products:

- If you still have trouble sleeping after 7 to 10 days, call your doctor.
- Take this drug at bedtime.
- Take this drug only 1 time per night.
- Take on an empty stomach.
- Do not take with or right after a meal.

Tablets:

- Take this drug right before you get into bed.
- Do not take this drug unless you can get a full night's sleep (at least 7 to 8 hours) before you need to be active again.

Extended-release tablets:

- Take this drug right before you get into bed.
- Swallow whole. Do not chew, break, or crush.
- Do not take this drug unless you can get a full night's sleep (at least 7 to 8 hours) before you need to be active again.

<u>Spray:</u>

- Take this drug right before you get into bed.
- Spray into mouth over the tongue.
- Prime pump before first use.
- Prime pump by spraying it 5 times.
- If you have not used the spray for more than 14 days, you will need to prime the pump with 1 spray or until you see a fine mist.
- Do not take this drug unless you can get a full night's sleep (at least 7 to 8 hours) before you need to be active again.

<u>All under the tongue (sublingual) tablets:</u>

- Be sure your hands are dry before you touch this drug.
- Place under tongue and let dissolve all the way. Do not chew, suck or swallow tablet.
- Do not eat, drink, or smoke while the tablet is dissolving.

Edluar:

- Take this drug right before you get into bed.
- Do not take this drug unless you can get a full night's sleep (at least 7 to 8 hours) before you need to be active again.

Intermezzo®:

- Take only as needed if you wake up in the middle of the night and have trouble going back to sleep. Only take a dose if you have 4 or more hours of bedtime left. Do not take more than 1 dose per night.
- Only keep 1 pouch with this drug in it at your bedside. Store all other pouches away from your bedside. Do not remove the drug from the pouch until you are ready to take a dose.

After you take this drug, leave the empty pouch where you can see it. This will help remind you that you have taken your dose.

What do I do if I miss a dose?

All products other than Intermezzo:

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If you 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 normal time.
- Do not take 2 doses at the same time or extra doses.
- Do not take more than 1 dose of this drug in the same day.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

Intermezzo®:

- If you take this drug on a regular basis, take a missed dose as soon as you think about it.
- If you will not be able to get 4 or more hours of sleep after taking the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- Do not take more than 1 dose of this drug in the same day.
- Many times this drug is taken on an as needed basis. Do not take more often than told by the doctor.

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

<u>All products:</u>

- Store at room temperature in a dry place. Do not store in a bathroom.
- Store this drug in a safe place where children cannot see or reach it, and where other people cannot get to it. A locked box or area may help keep this drug safe. Keep all drugs away from 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.

<u>Spray:</u>

• Store upright with the cap on.

- Do not freeze.
- Throw away after the stated number of sprays have been used, even if it feels like there is more drug left.

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.
- 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.

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