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Paliperidone

pronounced as (pal ee per' i done)

IMPORTANT WARNING:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as paliperidone have an increased risk of death during treatment. Older adults with dementia may also have a greater chance of having a stroke or ministroke during treatment.

Paliperidone is not approved by the Food and Drug Administration (FDA) for the treatment of behavior problems in older adults with dementia. Talk to the doctor who prescribed this medication, if you, a family member, or someone you care for has dementia and is taking paliperidone. For more information, visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

Why is this medication prescribed?

Paliperidone is used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions). Paliperidone is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

How should this medicine be used?

Paliperidone comes as an extended-release (long-acting) tablet to take by mouth. It is usually taken once a day in the morning with or without food. Take paliperidone at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take paliperidone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the tablets whole with plenty of water or other liquid. Do not split, chew, or crush the tablets. Tell your doctor if you cannot swallow tablets. Your doctor will probably prescribe another medication to treat your condition.

Talk to your doctor about how you are feeling during your treatment. If your symptoms are still bothersome, your doctor may gradually increase your dose, not more often than once every 5 days.

Paliperidone controls the symptoms of schizophrenia but does not cure the condition. Continue to take paliperidone even if you feel well. Do not stop taking paliperidone without talking to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking paliperidone,

- tell your doctor and pharmacist if you are allergic to paliperidone, risperidone (Risperdal), or any other medications.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: antidepressants; certain antibiotics such as erythromycin (E.E.S., E-Mycin, Erythrocin), gatifloxacin (Tequin) (not available in the United States), moxifloxacin (Avelox), and sparfloxacin (Zagam); certain antipsychotics such as chlorpromazine (Sonazine, Thorazine), pimozide (Orap), risperidone (Risperdal) and thioridazine; cisapride (Propulsid); levodopa (in Sinemet, in Stalevo); medications for anxiety, high blood pressure, or seizures; medications for irregular heartbeat such as amiodarone (Cordarone), disopyramide (Norpace), dofetilide (Tikosyn); procainamide (Procanbid, Pronestyl), quinidine (Quinidex), and sotalol (Betapace, Betapace AF); sedatives; sleeping pills; and tranquilizers. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had a prolonged QT interval (a rare heart problem that may cause fainting or irregular heartbeat); slow or irregular heartbeat; a heart attack; low levels of potassium or magnesium in your blood; seizures; trouble keeping your balance; a stroke; a head injury; a brain tumor; Parkinson's disease (a disorder of the nervous system that causes difficulties with movement, muscle control, and balance); diabetes; breast cancer; surgery involving the intestines; any condition that causes blockage or narrowing of the esophagus (tube that connects the mouth and stomach), stomach, or intestines such as cystic fibrosis (an inborn disease that causes problems with breathing, digestion, and reproduction), and inflammatory bowel disease (IBD; a group of conditions that cause swelling of the lining of the intestines); and kidney, heart, or liver disease. Also tell your doctor if you drink or have ever drunk large amounts of alcohol and if you use or have ever used street drugs or have overused prescription medications. Tell your doctor if you have ever had to stop taking a medication for mental illness because of severe side effects.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breast-feeding. If you become pregnant while taking paliperidone, call your doctor. Paliperidone may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking paliperidone.
- you should know that paliperidone may make you drowsy and may cause difficulty with thinking and movement. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that alcohol may add to the drowsiness caused by paliperidone. Do not drink alcoholic beverages while you are taking this medication.

- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you may be more likely to develop diabetes than people who do not have schizophrenia, and taking paliperidone or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking paliperidone: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause more serious symptoms, such as dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, or decreased consciousness, and may become life-threatening if it is not treated at an early stage.
- you should know that paliperidone may make it harder for your body to cool down when it gets very hot. Tell your doctor if you plan to exercise or be exposed to extreme heat.
- you should know that paliperidone may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking paliperidone or when your dose is increased. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Paliperidone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- dizziness, feeling unsteady, or having trouble keeping your balance
- extreme tiredness
- weakness
- headache
- dry mouth
- increased saliva
- weight gain
- stomach pain

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- fever
- muscle pain or stiffness
- falling

- confusion
- fast, pounding, or irregular heartbeat
- sweating
- unusual movements of your face or body that you cannot control
- slow or stiff movements
- restlessness
- painful erection of the penis that lasts for hours

Paliperidone may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include:

- unusual movements of your face or body that you cannot control
- slow or stiff movements
- restlessness
- unsteadiness
- drowsiness
- fast heartbeat

What other information should I know?

Keep all appointments with your doctor.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

You may notice something that looks like a tablet in your stool. This is just the empty tablet shell and does not mean that you did not get your complete dose of medication.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Invega[®]

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