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Paliperidone: Patient drug information

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

Brand Names: US Invega; Invega Sustenna; Invega Trinza

Brand Names: Canada Invega; Invega Sustenna; Invega Trinza

Warning

• There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.

What is this drug used for?

- · It is used to treat schizophrenia.
- · It is used to treat schizoaffective disorder.
- It may be given to you for other reasons. Talk with the doctor.

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

All products:

- If you have an allergy to paliperidone, risperidone, 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 kidney disease.
- If you have ever had a long QT on ECG or other heartbeat that is not normal.
- If you are taking any drugs that can cause a certain type of heartbeat that is not normal (prolonged QT interval). There are many drugs that can do this. Ask your doctor or pharmacist if you are not sure.

- If you are taking any of these drugs: Rifampin or St. John's wort.
- · If you are taking carbamazepine.

Tablets:

 If you have ever had any of these health problems: Cystic fibrosis; narrowing of the GI (gastrointestinal) tract or other GI problems like bowel block, small bowel disease, short gut syndrome, or slow-moving swallowing tube (esophagus) or bowel tract; peritonitis.

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.
- High blood sugar or diabetes, high cholesterol, and weight gain have happened with drugs like this one. These changes may raise the chance of heart and brain blood vessel disease. Talk with the doctor.
- Check your blood sugar as you have been told by your doctor.
- · Avoid drinking alcohol while taking this drug.
- Dizziness, sleepiness, and feeling less stable may happen with this drug. These may lead to falling. Broken bones or other health problems can happen from falling. Talk with the doctor.
- Low white blood cell counts have happened with drugs like this one. This may lead to a higher chance of
 getting an infection. Deadly infections have rarely happened. Tell your doctor if you have ever had a low
 white blood cell count. Call your doctor right away if you have signs of infection like fever, chills, or sore
 throat. Talk with your doctor.
- Some people who take this drug may get a very bad muscle problem called tardive dyskinesia. This muscle problem may not go away even if this drug is stopped. Sometimes, signs may lessen or go away over time after this drug is stopped. The risk of tardive dyskinesia may be greater in people with diabetes and in older adults, especially older women. The risk is also greater the longer you take this drug or with higher doses. Muscle problems may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or if you have muscle problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.
- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes
 these strokes have been deadly. This drug is not approved to treat mental problems caused by dementia.
 Talk with your doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect being able to get pregnant. This effect goes back to normal when the drug is stopped. If you have questions, talk with the doctor.

- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits
 and risks of using this drug while you are pregnant.
- Taking this drug in the third trimester of pregnancy may lead to muscle movements that cannot be controlled and withdrawal in the newborn. Talk with the doctor.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to 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:

All products:

- 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.
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- · Very bad dizziness or passing out.
- · Change in how you act.
- · Mood changes.
- · Shakiness, trouble moving around, or stiffness.
- · Slow heartbeat.
- · Trouble swallowing.
- Seizures.
- · More saliva.
- Any unexplained bruising or bleeding.
- · Not able to control eye movements.
- Not sweating during activities or in warm temperatures.
- Sex problems like lowered interest in sex or ejaculation problems.
- · Breast pain.
- · Enlarged breasts.
- · Nipple discharge.
- For women, no period.
- Call your doctor right away if you have a painful erection (hard penis) or an erection that lasts for longer than 4 hours. This may happen even when you are not having sex. If this is not treated right away, it may lead to lasting sex problems and you may not be able to have sex.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- A type of abnormal heartbeat (prolonged QT interval) can happen with this drug. Call your doctor right away if you have a fast heartbeat, a heartbeat that does not feel normal, or if you pass out.

Injection:

· Very bad irritation where the shot was given.

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:

All products:

- · Headache.
- · Weight gain.
- · Constipation.
- · Dizziness.
- · Feeling sleepy.
- · Anxiety.
- · Upset stomach or throwing up.
- · Nose and throat irritation.
- · Restlessness.
- · Feeling tired or weak.

Tablets:

You may see the tablet shell in your stool. This is normal and not a cause for concern.

Injection:

Irritation where the shot is given.

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.

Tablets:

- · Take with or without food.
- · Take with a full glass of water.
- · Swallow whole. Do not chew, break, or crush.
- To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- If you have trouble swallowing, talk with your doctor.

Injection:

· It is given as a shot into a muscle.

All products:

- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.
- It may take several weeks to see the full effects.
- Talk with your doctor before you use other drugs and natural products that slow your actions.

What do I do if I miss a dose?

Tablets:

- Take 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 take 2 doses at the same time or extra doses.

Injection:

Call your doctor to find out what to do.

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

Tablets:

- Store at room temperature.
- Store in a dry place. Do not store in a bathroom.

Injection:

· If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

All products:

- 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.

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