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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a694015.html>

Risperidone

pronounced as (ris 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 that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as risperidone 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. Tell your doctor and pharmacist if you are taking furosemide (Lasix).

Risperidone 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 risperidone. For more information visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

Why is this medication prescribed?

Risperidone 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) in adults and teenagers 13 years of age and older. It is also used to treat episodes of mania (frenzied, abnormally excited, or irritated mood) or mixed episodes (symptoms of mania and depression that happen together) in adults and in teenagers and children 10 years of age and older with bipolar disorder (manic depressive disorder; a disease that causes episodes of depression, episodes of mania, and other abnormal moods). Risperidone is also used to treat behavior problems such as aggression, self-injury, and sudden mood changes in teenagers and children 5 to 16 years of age who have autism (a condition that causes repetitive behavior, difficulty interacting with others, and problems with communication). Risperidone 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?

Risperidone comes as a tablet, a solution (liquid), and an orally disintegrating tablet (tablet that dissolves quickly in the mouth) to take by mouth. It is usually taken once or twice a day with or without

food. Take risperidone at around the same time(s) 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 risperidone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Use the dropper provided to measure your dose of risperidone oral solution. You can take the oral solution with water, orange juice, coffee, or low-fat milk. Do not take the solution with tea or cola.

Do not try to push the orally disintegrating tablet through the foil. Instead, use dry hands to peel back the foil packaging. Immediately take out the tablet and place it on your tongue. The tablet will quickly dissolve and can be swallowed with or without liquid. Do not chew or crush the tablet.

Your doctor will probably start you on a low dose of risperidone and gradually increase your dose to allow your body to adjust to the medication.

Risperidone may help control your symptoms but will not cure your condition. It may take several weeks or longer before you feel the full benefit of risperidone. Continue to take risperidone even if you feel well. Do not stop taking risperidone without talking to your doctor. If you suddenly stop taking risperidone, your symptoms may return and your illness may become harder to treat.

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 risperidone,

- tell your doctor and pharmacist if you are allergic to risperidone 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; carbamazepine (Tegretol); cimetidine (Tagamet); clozapine (Clozaril); dopamine agonists such as bromocriptine (Parlodel), cabergoline (Dostinex), levodopa (Dopar, Larodopa), pergolide (Permax), and ropinirole (Requip); medications for anxiety, high blood pressure, or seizures; other medications for mental illness; paroxetine (Paxil); phenobarbital (Luminal, Solfoton); phenytoin (Dilantin); quinidine (Quinaglute, Quinidex); ranitidine (Zantac); rifampin (Rifadin, Rimactane); sedatives; sleeping pills; tranquilizers; and valproic acid (Depakote, Depakene). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you use or have ever used street drugs or large amounts of alcohol; if you have ever overused prescription medications; if you have or have ever had Parkinson's disease (PD; a disorder of the nervous system that causes difficulties with movement, muscle control, and balance); dyslipidemia (high cholesterol levels); a low level of white blood cells in your blood or a decrease in white blood cells; difficulty swallowing; trouble keeping your balance; breast cancer; angina (chest pain); irregular heartbeat; high or low blood pressure; heart failure; a heart attack; a stroke; seizures; heart, kidney or liver disease; or if you or anyone in your family has or has ever had diabetes. Also 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 have severe vomiting or diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment.

- 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 breastfeeding. If you become pregnant while taking risperidone, call your doctor. Risperidone 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 risperidone.
- you should know that risperidone may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- you should know that alcohol can add to the drowsiness caused by this medication. Do not drink alcohol while taking risperidone.
- 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 are more likely to develop diabetes than people who do not have schizophrenia, and taking risperidone or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking risperidone: 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 that is not treated can cause a serious condition called ketoacidosis. Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include dry mouth, upset stomach and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.
- you should know that risperidone may make it harder for your body to cool down when it gets very hot or warm up when it gets very cold. Tell your doctor if you plan to do vigorous exercise or be exposed to extremely high or low temperatures.
- you should know that risperidone 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 risperidone. To avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- if you have phenylketonuria (PKU, an inherited condition in which a special diet must be followed to prevent damage to your brain that can cause severe intellectual disability), you should know that the orally disintegrating tablets contain phenylalanine.

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?

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

- nausea

- vomiting
- diarrhea
- constipation
- heartburn
- dry mouth
- increased saliva
- increased appetite
- weight gain
- stomach pain
- anxiety
- agitation
- restlessness
- dreaming more than usual
- difficulty falling asleep or staying asleep
- breast enlargement or discharge
- late or missed menstrual periods
- decreased sexual ability
- vision problems
- muscle or joint pain
- dry or discolored skin
- difficulty urinating
- dizziness, feeling unsteady, or having trouble keeping your balance

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

- fever
- muscle stiffness
- falling
- confusion
- fast or irregular pulse
- sweating
- unusual movements of your face or body that you cannot control
- faintness

- seizures
- slow movements or shuffling walk
- rash
- hives
- itching
- difficulty breathing or swallowing
- painful erection of the penis that lasts for hours

Risperidone may cause children to gain more weight than expected and for boys and male teenagers to have an increase in the size of their breasts. Talk to your doctor about the risks of giving this medication to your child.

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

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

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). Always store the orally disintegrating tablets in their sealed package, and use them immediately after opening the package.

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>]

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.

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 the following:

- drowsiness
- fast, pounding, or irregular heartbeat
- upset stomach
- blurred vision
- fainting
- dizziness
- seizures

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to risperidone.

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

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

- Risperdal[®] Oral Solution
- Risperdal[®] Tablets
- Risperdal[®] M-TAB[®] Orally Disintegrating Tablets

Last Revised - 01/15/2022

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National Library of Medicine 8600 Rockville Pike, Bethesda, MD 20894 U.S. Department of Health and Human Services

National Institutes of Health

Page last updated: 25 March 2022