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## Risperidone (Oral Route)

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### Risperidone (Oral Route)

Drug Information provided by: [Micromedex](#)

### US Brand Names

Risperdal

Risperdal M-Tab

### Description

Risperidone is used to treat the symptoms of psychotic disorders, such as schizophrenia, mania or bipolar disorder, or irritability associated with autistic disorder. This medicine should not be used to treat behavioral problems in older adult patients who have dementia.

This medicine is available only with your doctor's prescription.

Once a medicine has been approved for marketing for a certain use, experience may show that it is also useful for other medical problems. Although these uses are not included in product labeling, risperidone is used in certain patients with the following medical conditions:

- Tourette syndrome (inherited nerve, motor, and vocal disorder).

This product is available in the following dosage forms:

- Tablet, Disintegrating
- Tablet
- Solution

### Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against

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the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

## Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

## Pediatric

Appropriate studies have not been performed on the relationship of age to the effects of risperidone in children younger than 13 years of age with schizophrenia, in children younger than 10 years of age with bipolar disorder, or in children younger than 5 years of age with autistic disorder. Safety and efficacy have not been established.

## Geriatric

Although appropriate studies on the relationship of age to the effects of risperidone have not been performed in the geriatric population, geriatric-specific problems are not expected to limit the usefulness of risperidone in the elderly. However, elderly patients are more likely to be sensitive to the effects of risperidone, and have age-related liver, kidney, or heart problems, which may require an adjustment in the dose for patients receiving risperidone. This medicine should not be used for behavioral problems in older adults with dementia.

## Pregnancy

	Pregnancy Category	Explanation
All Trimesters	C	Animal studies have shown an adverse effect and there are no adequate studies in pregnant women OR no animal studies have been conducted and there are no adequate studies in pregnant women.

## Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

## Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

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Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

- Bepridil
- Cisapride
- Levomethadyl
- Mesoridazine
- Metoclopramide
- Pimozide
- Terfenadine
- Thioridazine

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Acecainide
- Ajmaline
- Amiodarone
- Amisulpride
- Amitriptyline
- Amoxapine
- Aprindine
- Arsenic Trioxide
- Asenapine
- Astemizole
- Azimilide
- Bretylium
- Chloral Hydrate
- Chloroquine
- Chlorpromazine

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- Citalopram
- Clarithromycin
- Desipramine
- Dibenzepin
- Disopyramide
- Dofetilide
- Dolasetron
- Doxepin
- Droperidol
- Encainide
- Enflurane
- Erythromycin
- Flecainide
- Fluconazole
- Foscarnet
- Gemifloxacin
- Ginkgo Biloba
- Halofantrine
- Haloperidol
- Halothane
- Hydromorphone
- Hydroquinidine
- Ibutilide
- Imipramine
- Isoflurane
- Isradipine
- Lidoflazine
- Linezolid

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- Lithium
- Lorcaïnide
- Mefloquine
- Milnacipran
- Nortriptyline
- Octreotide
- Pentamidine
- Pirmenol
- Prajmaline
- Probucoł
- Procainamide
- Prochlorperazine
- Propafenone
- Protriptyline
- Quetiapine
- Sematilide
- Sertindole
- Simvastatin
- Sotalol
- Spiramycin
- Sulfamethoxazole
- Sultopride
- Tedisamil
- Telithromycin
- Tetrabenazine
- Tramadol
- Trifluoperazine
- Trimethoprim

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- Trimipramine
- Vasopressin
- Zolmitriptan
- Zotepine

Using this medicine with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Bupropion
- Carbamazepine
- Cimetidine
- Fluoxetine
- Itraconazole
- Ketoconazole
- Lamotrigine
- Levorphanol
- Methadone
- Midodrine
- Paroxetine
- Phenobarbital
- Phenytoin
- Ranitidine
- Ritonavir
- Valproic Acid

## Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

## Other Medical Problems

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The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Aspiration pneumonia, risk or history of or
- Blood circulation problems or
- Dehydration or
- Dementia, such as decreasing mental ability or
- Difficulty swallowing—These conditions may increase the chance of serious side effects from the medicine.
  
- Breast cancer or
- Diabetes, or risk factors for diabetes or
- Drug abuse, history of or
- Epilepsy or other seizure disorders or
- Heart or blood vessel problems, including stroke and unusual heartbeats or
- Parkinson's disease—Risperidone may make these conditions worse.
  
- Kidney disease or
- Liver disease—Higher blood levels of risperidone may occur, increasing the chance of side effects.
  
- Other medical problems causing vomiting (e.g., brain tumor, bowel blockage, drug overdose, Reye's syndrome)—Risperidone may prevent vomiting and hide these medical problems from you and your doctor.
  
- Phenylketonuria (PKU)—The oral disintegrating tablets may contain aspartame, which can make your condition worse.

## Proper Use

Take this medicine only as directed by your doctor to benefit your condition as much as possible. Do not take more or less of it, do not take it more or less often, and do not take it for a longer or shorter time than your doctor ordered.

You may take this medicine with or without food.

For patients taking the oral solution:

- Measure the dose with the measuring device provided with your medicine. You can

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take the medicine directly from the measuring device or you can stir the dose into a small glass of water, coffee, orange juice, or low-fat milk just before taking it. Do not mix this medicine with cola or tea.

- Rinse the empty measuring device with water and place it back in its storage case. Put the plastic cap back on the bottle of medicine.

For patients taking the orally disintegrating tablet:

- Do not open the package until you are ready to take your medicine. To remove one tablet, separate one of the four tablets by tearing apart on perforations. Bend the corner as shown on the package. Peel back the foil to get to the tablet. Do not push the tablet through the foil because that could damage the tablet.
- Use dry hands and take the tablet out of the package and immediately place it on your tongue. The tablet needs to be used immediately because it cannot be stored once it is taken out of the package. Once the tablet is on your tongue it will disintegrate in seconds. You can swallow it with or without liquid. It is important not to split or chew the tablet.

## Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral dosage forms (solution, tablets, or orally disintegrating tablets):
  - For bipolar mania:
    - Adults—At first, 2 to 3 milligrams (mg) once a day. Your doctor may increase your dose as needed. However, the dose usually is not more than 6 mg per day.
    - Older adults—At first, 0.5 mg two times a day. The medicine can be given on a once a day schedule after your doctor has found the correct dose for you. Your doctor may increase your dose as needed. However, the dose usually is not more than 6 mg per day.
    - Children 10 to 17 years of age—At first, 0.5 mg once a day, in the morning or evening. Your doctor may increase your dose as needed.

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However, the dose usually is not more than 6 mg per day.

- Children younger than 10 years of age—Use and dose must be determined by your doctor.
- For irritability associated with autistic disorder:
  - Children 5 to 16 years of age weighing 20 kilograms (kg) or greater—At first, 0.5 milligrams (mg) per day . Your doctor may increase your dose as needed.
  - Children 5 to 16 years of age weighing less than 20 kg—At first, 0.25 mg per day. Your doctor may increase your dose as needed.
  - Children younger than 5 years of age—Use and dose must be determined by your doctor.
- For schizophrenia:
  - Adults—At first, 2 milligrams (mg) per day. Your doctor may increase your dose as needed. However, the dose usually is not more than 16 mg per day.
  - Older adults—At first, 0.5 mg two times a day. The medicine can be given on a once a day schedule after your doctor has found the correct dose for you. Your doctor may increase your dose as needed. However, the dose usually is not more than 6 mg per day.
  - Children 13 to 17 years of age—At first, 0.5 mg once a day in the morning or evening. Your doctor may increase your dose as needed. However, the dose usually is not more than 6 mg per day.
  - Children younger than 13 years of age—Use and dose must be determined by your doctor.

## Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

## Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

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Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

## Precautions

Your doctor will want to check your progress at regular visits, especially during the first few months of treatment with this medicine. This will allow for dose changes if they are necessary.

Do not stop taking this medicine without first checking with your doctor. Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This is to prevent side effects and to keep your condition from becoming worse.

This medicine may add to the effects of alcohol and other CNS depressants (medicine that makes you drowsy or less alert). Some examples of CNS depressants are antihistamines or medicine for hay fever, other allergies, or colds, sedatives, tranquilizers, or sleeping medicines, prescription pain medicine or narcotics, medicine for seizures or barbiturates, muscle relaxants; or anesthetics, including some dental anesthetics. Check with your doctor before taking any of the above while you are using this medicine.

Before having any kind of surgery, dental treatment, or emergency treatment, tell the medical doctor or dentist in charge that you are using this medicine. Taking risperidone together with medicines that are used during surgery, dental, or emergency treatments may increase the CNS depressant effects.

This medicine may cause blurred vision, dizziness, or drowsiness. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are not alert or able to see clearly.

Dizziness, lightheadedness, or fainting may occur, especially when you get up from a lying or sitting position. Getting up slowly may help. If the problem continues or gets worse, check with your doctor.

This medicine may make it more difficult for your body to keep a constant temperature. Use extra care not to become overheated during exercise or hot weather while you are taking this medicine, since overheating may result in heatstroke. Hot baths or saunas may make you feel dizzy or faint while you are taking this medicine. Also, use extra care not to become too cold while you are taking risperidone. If you become too cold, you may feel drowsy, confused, or clumsy.

Tardive dyskinesia (a movement disorder) may occur and may not go away after you stop using the medicine. Signs of tardive dyskinesia include fine, worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks, jaw, or arms and legs. Other serious but rare side effects may also occur. These include neuroleptic malignant syndrome (NMS), which may cause severe muscle stiffness, fever, severe tiredness or weakness, fast heartbeat, difficult breathing, increased sweating, loss of bladder control, or seizures. You and your doctor should discuss the good this medicine will do as well as the risks of taking it.

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## Side Effects

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

### More common

- Aggressive behavior
- Agitation
- Anxiety
- Changes in vision, including blurred vision
- Decreased sexual desire or performance
- Difficulty concentrating
- Difficulty speaking or swallowing
- Inability to move the eyes
- Loss of balance control
- Mask-like face
- Memory problems
- Menstrual changes
- Muscle spasms of the face, neck, and back
- Problems with urination or increase in the amount of urine
- Restlessness or need to keep moving (severe)
- Shuffling walk
- Skin rash or itching
- Stiffness or weakness of the arms or legs
- Tic-like or twitching movements
- Trembling and shaking of the fingers and hands
- Trouble sleeping
- Twisting body movements

### Less common

- Back pain

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- Chest pain
- Speech or vision problems
- Sudden weakness or numbness in the face, arms, or legs
- Unusual secretion of milk

## Rare

- Confusion
- Dizziness
- Drowsiness
- Extreme thirst
- Fast, shallow breathing
- Fast, weak heartbeat
- Headache
- Increased thirst
- Lip smacking or puckering
- Loss of appetite
- Muscle cramps
- Pale, clammy skin
- Poor coordination
- Prolonged, painful, inappropriate erection of the penis
- Puffing of the cheeks
- Rapid or worm-like movements of the tongue
- Shivering
- Talking, feeling, and acting with excitement and activity that cannot be controlled
- Uncontrolled chewing movements
- Uncontrolled twisting movements of neck, trunk, arms, or legs
- Unusual bleeding or bruising
- Unusual facial expressions or body positions

Some side effects may occur that usually do not need medical attention. These side

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effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

## More common

- Constipation
- Cough
- Diarrhea
- Dry mouth
- Headache
- Heartburn
- Increased dream activity
- Increased length of sleep
- Nausea
- Sleepiness or unusual drowsiness
- Sore throat
- Stuffy or runny nose
- Unusual tiredness or weakness
- Weight gain

## Less common

- Body aches or pain
- Chills
- Dandruff
- Darkening of skin color
- Dry skin
- Ear congestion
- Fever
- Increase in body movements
- Increased watering of the mouth
- Joint pain

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- Loss of voice
- Oily skin
- Pain or tenderness around the eyes and cheekbones
- Shortness of breath or troubled breathing
- Sneezing
- Stomach pain
- Tightness of the chest or wheezing
- Toothache
- Vomiting
- Weight loss

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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