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Drug Information: Risperidone (Systemic)

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Brand Names

In the U.S.—

- Risperdal

In Canada—

- Risperdal

Category

- Antipsychotic

Description

Risperidone (ris-PER-i-done) is used to treat the symptoms of psychotic disorders, such as schizophrenia.

Risperidone is available only with your doctor's prescription, in the following dosage forms:

Oral

- Oral solution (U.S. and Canada)
- Tablets, Orally disintegrating (U.S.)
- Tablets (U.S. and Canada)

Before Using This Medicine

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For risperidone, the following should be considered:

Allergies—Tell your doctor if you have ever had any unusual or allergic reaction to risperidone. Also tell your health care professional if you are allergic to any other substances, such as foods, preservatives, or dyes.

Pregnancy—Studies with risperidone have not been done in pregnant women. One baby whose mother took risperidone during pregnancy was born with a serious brain problem. However, it is not known whether this problem was caused by risperidone. Some unwanted effects have been reported in animal studies, but the risk to human babies is not clear. Before taking this medicine, make sure your doctor knows if you are pregnant or if you may become pregnant.

Breast-feeding—Risperidone passes into human milk and may cause unwanted effects, such as behavior changes, in nursing babies. It may be necessary for you to take another medicine or to stop breast-feeding during treatment. Be sure you have discussed the risks and benefits of the medicine with your doctor.

Children—Studies on this medicine have been done only in adult patients, and there is no specific information comparing use of risperidone in children with use in other age groups.

Older adults—Elderly people may be especially sensitive to the effects of risperidone. This may increase the chance of having side effects during treatment.

Other medicines—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 risperidone, it is especially important that your health care professional know if you are taking any of the following:

- Amiodarone [e.g., Cordarone] or
- Amitriptyline [e.g., Elavil] or
- Arsenic trioxide [e.g., Trisenox] or
- Bepridil [e.g., Vascor] or
- Chlorpromazine [e.g., Thorazine] or
- Cisapride [e.g., Propulsid] or
- Clarithromycin [e.g., Biaxin] or
- Clomipramine [e.g., Anafranil] or
- Clozapine [e.g., Clozaril] or
- Desipramine [e.g., Norpramin] or
- Disopyramide [e.g., Norpace] or
- Dofetilide [e.g., Tikosyn] or
- Dolasetron [e.g., Anzemet] or
- Droperidol [e.g., Inapsine] or
- Erythromycin [e.g., E-mycin] or
- Gatifloxacin [e.g., Tequin] or
- Halofantrin [e.g., Halfan] or
- Haloperidol [e.g., Haldol] or
- Ibutilide intravenous injection [e.g., Covert] or
- Levofloxacin [e.g., Leaquin] or
- Levomethadyl [e.g., Orlaam] or
- Mefloquine [e.g., Lariam] or
- Mesoridazine [e.g., Serentil] or

- Moxifloxacin [e.g., Avelox] or
 - Ondansetron [e.g., Zofran] or
 - Pimozide [e.g., Orap] or
 - Procainamide [e.g., Procainbid, Pronestyl] or
 - Propafenone [e.g., Rythmol] or
 - Quinidine [e.g., Quinaglute, Quinidex] or
 - Sotalol [e.g., Betapace, Sorine] or
 - Sumatriptan [e.g., Imitrex] or
 - Thioridazine [e.g., Mellaril] or
 - Ziprasidone [e.g., Geodon] or
 - Zolmitriptan [e.g., Zomig]—These medicines may increase the chance of serious side effects and should not be taken with risperidone
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- Alcohol or
 - Antihypertensives (high blood pressure medicine) or
 - Central nervous system (CNS) depressants (medicine that makes you drowsy or less alert) or
 - Tricyclic antidepressants (amitriptyline [e.g., Elavil], amoxapine [e.g., Asendin], clomipramine [e.g., Anafranil], desipramine [e.g., Norpramin], doxepin [e.g., Sinequan], imipramine [e.g., Tofranil], nortriptyline [e.g., Aventyl], protriptyline [e.g., Vivactil], trimipramine [e.g., Surmontil])—Risperidone may add to the effects of these medicines, causing unwanted effects such as increased drowsiness or low blood pressure
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- Bromocriptine (e.g., Parlodel) or
 - Levodopa (e.g., Larodopa, Sinemet) or
 - Pergolide (e.g., Permax)—Risperidone may interfere with the effects of these medicines so that they do not work properly
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- Carbamazepine (e.g., Epitol, Tegretol) or
 - Clozapine (e.g., Clozaril) or
 - Fluoxetine (e.g., Prozac, Sarafem)—These medicines may affect the blood levels of risperidone so that risperidone does not work properly or causes unwanted effects. Your doctor may need to change your dose of risperidone

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

- Breast cancer or
 - Heart or blood vessel problems, including stroke and unusual heartbeats or
 - Parkinson's disease—Risperidone may make these conditions worse
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- Dehydration or
 - Blood circulation problems—These conditions may increase the chance of side effects from the medicine
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- Dementia, such as decreasing mental ability or
 - Difficulty swallowing—These conditions may increase the chance of side effects from the medicine
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- Epilepsy or other seizure disorders—Risperidone may increase the risk of having seizures

- 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

Proper Use of This Medicine

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.

Dosing—

The dose of risperidone 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 risperidone. *If your dose is different, do not change it unless your doctor tells you to do so.*

- For symptoms of psychotic disorder:
 - For *oral solution* dosage form—
 - Adults—At first, 1 milligram (mg) [1 milliliter (mL)] per day. The medicine can be given on a once a day or twice a day schedule. Your doctor may increase your dose as needed. However, the dose usually is not more than 16 mg (16 mL) a day.
 - Children younger than 18 years of age—Use and dose must be determined by the doctor.
 - Older adults—At first, 0.25 mg or 0.5 mg (0.5 mL) 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 3 mg (3 mL) a day.
 - For *oral tablet* dosage form—
 - Adults—At first, 1 milligram (mg) per day. The medicine can be given on a once a day or twice a day schedule. Your doctor may increase your dose as needed. However, the dose usually is not more than 16 mg a day.
 - Children younger than 18 years of age—Use and dose must be determined by the doctor.
 - Older adults—At first, 0.25 mg or 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 3 mg a day.

For patients taking the *oral solution* form of risperidone:

- Measure the dose with the measuring device provided with your medicine. Stir the dose into a small glass (3 to 4 ounces) 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* form of risperidone:

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 can not 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.*

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—

To store this medicine:

- Keep out of the reach of children.
- Store away from heat and direct light.
- Do not store the tablet form of this medicine in the bathroom, near the kitchen sink, or in other damp places. Heat or moisture may cause the medicine to break down.
- Keep the solution form of this medicine from freezing.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

Precautions While Using This Medicine

Your doctor should check your progress at regular visits, especially during the first few months of treatment with this medicine. This will allow the dosage to be changed if necessary to meet your needs.

Do not stop taking this medicine without first checking with your doctor. Your doctor may want you to reduce gradually 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 medicine; prescription pain medicine or narcotics; barbiturates; medicine for seizures; 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.

Risperidone may cause your skin to be more sensitive to sunlight than it is normally. Exposure to sunlight, even for brief periods of time, may cause a skin rash, itching, redness or other discoloration of the skin, or a severe sunburn. When you begin taking this medicine:

- Stay out of direct sunlight, especially between the hours of 10:00 a.m. and 3:00 p.m., if possible.
- Wear protective clothing, including a hat. Also, wear sunglasses.
- Apply a sun block product that has a skin protection factor (SPF) of at least 15. You may require a product with a higher SPF number, especially if you have a fair complexion. If you have any questions about this, check with your health care professional.
- Apply a sun block lipstick that has an SPF of at least 15 to protect your lips.
- Do not use a sunlamp or tanning bed or booth.

If you have a severe reaction from the sun, 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.

Side Effects of This Medicine

Side Effects of This Medicine

Along with its needed effects, risperidone can sometimes cause serious side effects. 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.*

Stop taking risperidone and get emergency help immediately if any of the following side effects occur:

- *Rare*
 - Convulsions (seizures); difficult or fast breathing; fast heartbeat or irregular pulse ; fever (high); high or low blood pressure; increased sweating; loss of bladder control; muscle stiffness (severe); unusually pale skin; unusual tiredness or weakness (severe)

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

- *More common*
 - Difficulty in speaking or swallowing; inability to move eyes; muscle spasms of face, neck, and back; twisting movements of body
- *Less common*
 - speech or vision problems; sudden weakness or numbness in the face, arms or legs

- *Rare*
 - High body temperature (dizziness; fast, shallow breathing; fast, weak heartbeat; headache; muscle cramps; pale, clammy skin; increased thirst) ; lip smacking or puckering; low body temperature (confusion, drowsiness, poor coordination, shivering) ; prolonged, painful, inappropriate erection of the penis; puffing of cheeks; rapid or worm-like movements of tongue; uncontrolled chewing movements; uncontrolled movements of arms and legs

Check with your doctor as soon as possible if any of the following side effects occur:

- *More common*
 - Anxiety or nervousness; changes in vision, including blurred vision; decreased sexual desire or performance; loss of balance control; mask-like face; menstrual changes; mood or mental changes, including aggressive behavior, agitation, difficulty in concentration, and memory problems; problems in urination or increase in amount of urine; restlessness or need to keep moving (severe); shuffling walk; skin rash or itching; stiffness or weakness of arms or legs; tic-like or twitching movements; trembling and shaking of fingers and hands; trouble in sleeping
- *Less common*
 - Back pain; chest pain; unusual secretion of milk
- *Rare*
 - Extreme thirst; increased blinking or spasms of eyelid; loss of appetite; talking, feeling, and acting with excitement and activity that cannot be controlled; uncontrolled twisting movements of neck, trunk, arms, or legs; unusual bleeding or bruising; unusual facial expressions or body positions

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

- *More common*
 - Constipation; coughing; diarrhea; drowsiness; dryness of 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*
 - Back pain; body aches or pain; chills; dandruff; darkening of skin color; dry skin; ear congestion; fever; increase in body movements; increased sensitivity of the skin to sun; increased watering of mouth; joint pain; loss of voice; nasal congestion; oily skin; pain or tenderness around eyes and cheekbones; shortness of breath or troubled breathing; sneezing ; stomach pain; toothache ; tightness of chest or wheezing; vomiting; weight loss

Some side effects, such as uncontrolled movements of the mouth, tongue, and jaw, or uncontrolled movements of arms and legs, may occur after you have stopped taking this medicine. If you notice any of these effects, check with your doctor as soon as possible.

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

Developed: 09/12/1995

Revised: 06/19/2003

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