

## Risperdal (risperidone)

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### **FDA ALERT [08/2007] INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. RISPERDAL® (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis.

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### **Brand and Generic Names:**

Available forms...

- Risperdal® tablets or liquid.
  - Tablets: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
  - Liquid: 1 mg/ml liquid in a 30 ml bottle (there is 5 mg in one teaspoonful)
- Risperdal M-Tab® - a rapidly disintegrating tablet
  - 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg
- [Risperdal Consta® - a long-acting injection](#)

– 25 mg, 37.5 mg, or 50 mg for intramuscular injection

- Generic name = risperidone

### **What is Risperdal® and what does it treat?**

Risperidone is an antipsychotic medication approved to treat schizophrenia, and acute mania or mixed episodes of bipolar disorder. Risperidone can improve symptoms of schizophrenia such as: hallucinations, delusions, and disorganized thinking; in some people, improvement in social isolation, reduced speech productivity and motivation also occur. Risperidone can improve symptoms of mania which include: racing thoughts, having inflated self esteem or an elevated mood, impulsivity, irritability and decreased need for sleep.

Risperidone is also approved to treat children and adolescents (ages 5-16 years) who have irritability associated with autistic disorder. Risperidone can improve symptoms of autistic disorder such as: aggression toward others, self-injurious behaviors, temper tantrums, and rapidly changing moods.

While not approved by the FDA for other uses, risperidone may be used alone or with other medications to treat symptoms such as agitation or other behavior problems in older persons with memory loss or people with developmental disabilities, children with mental illnesses like schizophrenia or bipolar disorder, or depression. It may also be used for long-term management of bipolar disorder or Tourette's disorder.

### **What is the most important information I should know about Risperdal®?**

Relapse is very common in schizophrenia and bipolar disorder and the most frequent cause is that patients stop taking their medication. Even when medication is taken exactly as prescribed, relapse may still occur for some people. Therefore it is recommended that you take your medication exactly as prescribed by your healthcare provider as this has been shown to decrease relapse.

- Schizophrenia and bipolar disorder require long-term treatment. Only your healthcare provider can determine the length of risperidone treatment that is right for you.

Children receiving risperidone for irritability associated with autistic disorder should be monitored closely. If your child responds well to risperidone and treatment is to be continued, your child's health care provider may decide to lower the dose to allow for the maximum benefit and fewest side effects.

- Do not stop taking risperidone, or change your or your child's dose, without talking to your healthcare provider first.
- Some people may develop side effects on risperidone such as extrapyramidal effects (restlessness, tremor, stiffness) or tardive dyskinesia (slow or jerky movements that one

cannot control, often starting in the mouth with tongue rolling or chewing movements). These symptoms are likely to be less severe and occur less often than with the older antipsychotic medications (e.g.,: Haldol® [haloperidol], Prolixin® [fluphenazine], Thorazine® [chlorpromazine]). If you develop movements that you cannot control, call your healthcare provider immediately.

- Risperidone treatment may be associated with strokes and/or transient ischemic attacks (TIAs) in elderly people with dementia and accompanying behavior problems. This safety concern has not been proven confidently, but there is some evidence. Talk with your health care provider if you are concerned or have questions.
- Risperidone treatment must be monitored by a healthcare provider. Be sure to keep all of your scheduled appointments so that you stay healthy while on risperidone.
- You should not take illegal drugs or drink alcohol while taking risperidone.

### **What should I discuss with my healthcare provide before taking Risperdal®?**

- Symptoms of schizophrenia and/or bipolar disorder that are bothersome to you.
- Symptoms of autistic disorder that are bothersome to you or your child.
- The medications you have taken in the past for schizophrenia, bipolar disorder, or autistic disorder. It would be helpful for your provider to know which medications were effective and which were not.
- If you had any serious side effects to other antipsychotic medications like muscle stiffness, muscle cramping, shaking, tardive dyskinesia, neuroleptic malignant syndrome, weight gain, or diabetes, tell your healthcare provider.
- All other medications you are currently taking.
- If you smoke cigarettes, use illegal drugs, or drink alcohol.
- About any medication allergies you have.
- If you are pregnant, plan to get pregnant, or are breast feeding.
- What medical problems you have, especially diabetes, high cholesterol or triglycerides, increased body weight, irregular heart beats, or seizures.
- Tell your doctor if you have thoughts of suicide.

## **How should I take Risperdal®?**

- Risperidone is usually taken once or twice daily. Most patients begin at a low dose and it is increased slowly over several weeks.
- Risperidone can be taken with or without food.
- Use a calendar or pill box to help you remember to take your medication. Or, have a family member or friend remind you check in with you to be sure you are taking your medication.
- The dose that is right for you will be determined by your healthcare provider. Most patients take 6 mg or less a day. The dose for children or adolescents with autistic disorder may be based on their body weight. Most children take doses less than 3 mg /day. There is no dosing information for children who weigh less than 15 kg (33 pounds).
- Risperidone liquid should NOT be taken with tea or cola, it may be taken with water, orange juice, coffee, or low fat milk.
- If you are just starting the Risperdal Consta® injection, then there will be an overlap of three weeks of oral tablets in order to allow the injection to start working.

## **What happens if I miss a dose?**

If a dose of risperidone is missed, take it as soon as you remember it, if it is not too close to when your next dose is due—discuss this with your health care provider. Do not double your next dose or take more than what is prescribed.

## **What should I avoid while taking Risperdal®?**

- Avoid smoking cigarettes, using illegal drugs, or drinking alcohol.
- Avoid overexposure to the sun. Use sunscreen with at least SPF 15 and wear light colored clothing. Wear a hat to protect your head and face.
- Some people get drowsy on risperidone, avoid driving a car until you are sure how the medication will affect you.

## **What happens if I overdose?**

- If an overdose occurs, whether intentional or accidental, immediate medical attention is necessary. Call your doctor or emergency medical service (911).
- The following may occur in an overdose: increased heart rate, low blood pressure, sedation, extrapyramidal symptoms, seizures, irregular heart rhythms. In severe cases, people can develop coma and death is possible.

## **What are the possible side effects of Risperdal®?**

Risperidone's more common side effects are usually relatively minor, especially when taken at doses of 6 mg/day or less. Some people may experience low blood pressure or dizziness, especially when standing up suddenly; heart palpitations; sleepiness; constipation; weight gain; sexual dysfunction; and fatigue. Some of these problems may be reduced by increasing the dose slowly. Patients who already have low blood pressure, have kidney or liver impairment, are elderly, or are in a weakened condition may require close monitoring and even more gradual dose adjustment. These side effects may also include extrapyramidal symptoms (muscle stiffness, tremors, and body shakes). At higher doses, extrapyramidal side effects often increase. Cogentin (benztropine) or Benadryl (diphenhydramine) can be prescribed to reduce or eliminate stiffness and tremors.

More serious side effects include weight gain, diabetes, high cholesterol and triglycerides, neuroleptic malignant syndrome, seizures, or increased blood levels of prolactin which may (for example) result in females losing their period and males losing their sex drive.

In some clinical trials, it was determined that elderly people treated with risperidone developed strokes at a higher rate than those on placebo medication (sugar pill). It is not known at this time if risperidone causes stroke.

## **Are there any risks for taking this medication for long periods of time?**

Tardive dyskinesia (TD) is a side that develops with prolonged use of antipsychotics. Medications such as risperidone have been shown to have a much lower risk of TD compared to older antipsychotics, such as Haldol (haloperidol). Should you develop symptoms of TD, such as grimacing, sucking and smacking of lips, and other movements that you cannot control, contact your healthcare provider immediately.

Risperdal is thought to have a lower risk of weight gain than some of the other atypical antipsychotics. No one can predict how much weight a person will gain on any medicine, but an approach that includes exercise and diet and monitoring for weight gain and diabetes will be well placed.

## **What other drugs interact with this medication?**

Some antidepressants, such as Prozac (fluoxetine) and Paxil (paroxetine) may increase the blood levels of risperidone. It is possible that patients taking risperidone with either of these agents may experience a change in side effects. Tell your doctor if you begin or discontinue fluoxetine or paroxetine therapy.

Some medications, such as Tegretol (carbamazepine), Dilantin (phenytoin), phenobarbital, or rifampin (Rifadin) may decrease the blood levels of risperidone. It is possible that you may experience a decreased effect from risperidone if you also take one

of these other medications. Tell your doctor if you begin or discontinue any of these treatments.

**How long does it take for Risperdal® to work?**

Risperidone, like some of the other newer antipsychotics, blocks the action of the neurotransmitters dopamine and serotonin. Older antipsychotics seem to primarily affect only dopamine.

Improvement of some symptoms may be noticed in some patients within a few weeks. The full benefit of risperidone may not be seen for 4-6 weeks.

*Updated by Mary C. Barovica, Pharm.D., BCPP  
(February 2007)*



**For further information please contact the pharmaceutical company listed below.**

Janssen Pharmaceutica, Inc.	1125 Trenton- Harbourton Rd.  Titusville, NJ 08560	800-526-7736  (800- JANSSEN)	<a href="http://www.janssen.com">www.janssen.com</a>
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**Free or low-cost medications provided by pharmaceutical companies**

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

**Risperdal Rx Assistance Program:** (800) 652-6227