



Risperdal/Risperdal M-Tab/ Risperdal Consta (risperidone)

Generic name: Risperidone

Available strengths: 0.25 mg, 0.5 mg, 1 mg, 2 mg,
3 mg, 4 mg tablets; 0.5 mg, 1 mg,
2 mg rapid-disintegrating tablets (Risperdal M-Tab);
1 mg/mL oral solution; 25 mg, 37.5 mg, 50 mg
long-acting injection (Risperdal Consta)

Available in generic: No

Drug class: Second-generation antipsychotic

General Information

Risperdal (risperidone) is a **serotonin and dopamine antagonist** belonging to the class of second-generation antipsychotics that are often called *atypical* antipsychotics. (Refer to the handout on “Second-Generation Antipsychotics” for an explanation of how these antipsychotics work.) These agents are atypical in that they are significantly different, both in structure and pharmacology, from the older, *typical* antipsychotic medications such as Thorazine (chlorpromazine), Mellaril (thioridazine), and Haldol (haloperidol). The second-generation antipsychotics block both serotonin and dopamine receptors, whereas the typical antipsychotics are mainly dopamine-receptor antagonists.

The U.S. Food and Drug Administration approved Risperdal for treatment of schizophrenia and acute mania in bipolar disorder. The use of a medication for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe medications for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of those treatments. Like other second-generation antipsychotics, Risperdal may be used to treat other psychiatric disorders, including schizoaffective disorder, psychotic depression, severe obsessive-compulsive disorder, and psychosis in Alzheimer’s disease and other neuropsychiatric disorders.

Dosing Information

The recommended starting dosage for Risperdal is 0.5–1 mg twice a day. The dosage may be increased after 1–2 weeks to 2 mg twice a day. After several weeks, if needed, the dosage may be gradually increased to 3 mg

twice a day. The usual therapeutic dosage is between 4 mg/day and 6 mg/day. Some patients may require a dosage as high as 8 mg/day, but patients generally have fewer side effects if they take less than 6 mg/day. Risperdal can also be taken once a day, usually at bedtime. However, some patients, especially seniors, may not tolerate once-a-day dosing because a single dose may be associated with a higher incidence of side effects. The current practice with Risperdal is to start with a low dosage and increase slowly, particularly with seniors.

Risperdal comes in a rapid-disintegrating tablet form (Risperdal M-Tab), which dissolves in the mouth. It also comes in a solution that can be mixed in water or other liquids, but it is not compatible with tea or cola.

Risperdal Consta is a long-acting injectable form of Risperdal. The recommended starting dosage is 25 mg every 2 weeks. It takes about 3 weeks for Risperdal Consta to build up adequate blood levels, thus oral Risperdal or another antipsychotic medication must be continued for 3 weeks after the first dose of Risperdal Consta is given in order to prevent worsening of symptoms. Most patients' symptoms respond to 25 mg given every 2 weeks. If symptoms do not respond to 25 mg, a higher dosage of 37.5 or 50 mg every 2 weeks may be needed. The dosage should not exceed the maximum of 50 mg every 2 weeks.

Common Side Effects

At lower dosages, Risperdal is generally well tolerated. Common side effects include sedation, dizziness, headache, nausea, vomiting, constipation, insomnia, and agitation. There is a higher incidence of **extrapyramidal symptoms** (EPS) when the dosage of Risperdal exceeds 6 mg/day. EPS are neurological disturbances produced by antipsychotics (or other causes) in the area of the brain that controls motor coordination. These side effects include muscle rigidity, tremors, drooling, restlessness, a “mask-like” facial expression, shuffling gait, and muscle spasms that result in abnormal posture (**dystonia**). EPS mimic Parkinson's disease, and many of the signs and symptoms are common in both conditions. Some patients experience **akathisia**, which is a subjective sense of restlessness accompanied by fidgeting and inability to sit or stand still. EPS may be managed by decreasing the antipsychotic dosage or adding another medication (anticholinergic medication) to counteract the side effect.

Generally, Risperdal does not induce significant weight gain as compared with some other antipsychotics. Control of weight can usually be managed by diet and exercise without stopping Risperdal.

Risperdal may block a compensatory response—the narrowing of blood vessels—that counterbalances postural change, resulting in a momentary drop in blood pressure when the person rises too rapidly, which may cause dizziness and lightheadedness. This reaction is known as **orthostatic hypotension**. Patients, especially seniors and those taking antihypertensive medications, need to be cautious and rise slowly to allow their body to adjust to the change in position, avoiding a sudden drop in their blood pressure.

Adverse Reactions and Precautions

Risperdal may cause drowsiness and sedation and impair physical coordination and mental alertness. Patients should avoid potentially dangerous activities, such as driving a car or operating machinery, until they are sure that these side effects will not affect their ability to perform these tasks.

Tardive dyskinesia (TD) is a potential adverse reaction from antipsychotic medications. It consists of abnormal involuntary movements. It is a potentially irreversible condition that includes “pill-rolling” movements of the fingers, darting and writhing movements of the tongue, lip puckering, facial grimacing, and shoulder or neck movements. The risk of TD is believed to increase as the duration of treatment and the total cumulative amount of antipsychotic medications prescribed to the patient increases. The risk of TD associated with second-generation antipsychotics is significantly lower than with conventional antipsychotics.

Neuroleptic malignant syndrome (NMS) is a rare, toxic reaction to antipsychotics. The symptoms are severe muscle stiffness, rigidity, elevated body temperature, increased heart rate and blood pressure, irregular

pulse, and sweating. NMS may lead to delirium and coma. It can be fatal if medical intervention is not immediately provided. There is no test to predict whether an individual may be susceptible to developing NMS when exposed to an antipsychotic. Thus NMS must be recognized early because it is a medical emergency that requires immediate discontinuation of the antipsychotic, hospitalization, and intensive medical treatment.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Risperdal has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. In animal studies, there was no evidence of harm to the fetus when exposed to Risperdal. Animal studies, however, are not always predictive of effects in humans. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their psychosis when they stop Risperdal. In these circumstances, the physician may discuss the need to restart the medication or seek an alternative medication or treatment.

Nursing mothers should not take Risperdal, because small amounts will pass into breast milk and be ingested by the baby. If stopping the antipsychotic is not an alternative, breastfeeding should not be started or should be discontinued.

Possible Drug Interactions

Some medications when taken with Risperdal may result in drug interactions that alter their levels, which may produce undesired reactions. The possible drug interactions with Risperdal are summarized in the table below.

Selective serotonin reuptake inhibitors (SSRIs)	Prozac, Paxil, and other SSRI antidepressants may decrease the metabolism of Risperdal, thus increasing Risperdal blood levels and the likelihood of unwanted side effects.
Nizoral (ketoconazole), Diflucan (fluconazole), and Sporanox (itraconazole)	These antifungal agents may decrease the metabolism of Risperdal, thus increasing Risperdal blood levels and the likelihood of unwanted side effects.
Tegretol (carbamazepine)	Tegretol can decrease the blood levels of Risperdal, making it less effective in treating the symptoms of the illness.

Patients taking Risperdal should not consume alcohol because the combination may impair thinking, judgment, and coordination.

Overdose

The most common signs of Risperdal overdose include extreme sedation, orthostatic hypotension, confusion, rapid heart rate, muscle rigidity, and seizures. The outcome depends on the amount ingested and whether Risperdal was combined with other medications.

