

RISPERDAL[®] TABLETS/ORAL SOLUTION

Risperidone (1 mg, 2 mg, 1 mg/ml)

What is in this leaflet

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What RISPERDAL[®] is used for

RISPERDAL[®] is used to treat a group of disorders called psychoses (e.g. schizophrenia). These are brain function disorders relating to thought, feeling and/or action, such as confusion, impaired perception (like hearing the voice of someone who is not there), unusual suspiciousness, alienation from society, and being excessively introverted, as well as the resulting disturbed mental state, anxiety, and tension.

RISPERDAL[®] may be taken for both sudden (acute) and long-lasting (chronic) psychotic disorders.

In addition, after symptoms have been relieved, RISPERDAL[®] is used to keep the disorder under control, i.e. to prevent its recurrence.

RISPERDAL[®] is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorders.

RISPERDAL[®] is used to treat short-term treatment (up to 6 weeks) of long-term aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

How RISPERDAL[®] works

RISPERDAL[®] helps to correct the chemical imbalance in the brain associated with these conditions.

Before you use RISPERDAL[®]

- When you must not use it

Do not take RISPERDAL[®] if you know that you are oversensitive to Risperidone or other ingredients listed at the end of

the leaflet. Oversensitivity can be recognized for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

- Before you start to use it

Always inform your doctor or pharmacist if you are using other medicines because some medicines should not be taken together.

Tell your doctor if:

- you or someone else in your family has a history of blood clots. Blood clots in the lungs can be fatal.
- you know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines).
- you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.
- you have blood vessel disease, diabetes, impaired kidney or liver function, Parkinson's disease, declining in memory or epilepsy. Medical supervision might be necessary while you take RISPERDAL[®] and the dosage might have to be adjusted.
- you have heart problems, particularly irregular rhythm, abnormalities in electrical activity of the heart.
- you have or are at risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking RISPERDAL[®] and regularly during treatment.

Pregnancy and Breast-feeding

If you are pregnant or if you are planning to become pregnant, you should inform your doctor, who will decide if you can take RISPERDAL[®]. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, or difficulty in feeding may occur in newborns if a mother used RISPERDAL[®] in the last trimester of her pregnancy.

Do not breast-feed if you are taking RISPERDAL[®]. Consult your doctor in that case.

- Taking other medicines

Inform your doctor if you are taking any other medicine. Your doctor will tell you which medicines you can use along with RISPERDAL[®]. Inform your doctor if you are taking:

- alcohol
- medicines that reduced the ability to react (e.g., "tranquilizers", narcotic painkillers, certain antihistamines, certain antidepressants)
- some medicines for treating Parkinson's disease (e.g. dopamine agonists, levodopa)
- medicines that increase the activity of the central nervous system (psychostimulants such as methylphenidate)
- medicines for high blood pressure
- medicines that may change the electrical activity of the heart, such as but not restricted to medicines for malaria, heart rhythm disorders, allergies, other antipsychotics, "water tablets" or other medicines affecting body salts (sodium, potassium, magnesium).

Some medicines, when they are taken together with RISPERDAL[®], may increase or decrease the level of RISPERDAL[®] in your blood. Therefore, tell your doctor if you start and/or stop taking any of the below medicines since your doctor may need to change the dose.

Medicines that can increase the level of RISPERDAL[®] in your blood:

- Fluoxetine and paroxetine, medicines mainly used to treat depression and various anxiety disorders;
- Itraconazole and ketoconazole, medicines for treating fungal infections;
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir;
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm;
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

Medicines that can decrease the level of RISPERDAL® in your blood:

- Carbamazepine, a medicine mainly used for epilepsy
- Rifampicin, a medicine for treating some infections such as tuberculosis

Taking RISPERDAL® with furosemide, a medicine used to treat conditions such as heart failure and high blood pressure, may be associated with harmful effects in elderly people with dementia (impairment in memory, thinking and communication). Tell your doctor if you are taking furosemide.

How to use RISPERDAL®

RISPERDAL® comes in the form of oral tablets for swallowing and a solution, all of which are to be taken only by mouth.

You may take RISPERDAL® either together with or between meals. The oral tablets may be taken with some liquid. The solution should be mixed with any non-alcoholic drink, except for tea.

It is very important that the correct amount of RISPERDAL® be taken, but this will vary from person to person. That is why your doctor will adjust the amount until the desired effect is obtained. So follow your doctor's instructions carefully and do not change or stop the required dosage without consulting him or her first.

- How much to use

For psychoses (e.g. schizophrenia) in adults, treatment starts gradually. For example: 2 mg is taken the first day and 4 mg the second day. From then on, the dose can remain unchanged or further modified if necessary.

For long-term treatment, 4 to 6 mg daily is the usual dose. A lower dose, however, may be sufficient.

The total amount per day can be taken in one intake or can be divided over two intakes, one in the morning and one in the evening.

Your doctor should advise you which is the best for you.

For psychoses in elderly people, it is generally best to start with 0.5 mg twice

a day. The medication can be gradually increased to 1 to 2 mg twice a day. Your doctor will tell you how many tablets or how much solution is appropriate to your situation.

Experience with this treatment in children aged less than 18 years is lacking.

For the treatment of bipolar mania, it should be administered on a once daily schedule, starting with 2 mg risperidone. Dosage adjustments, if indicated, should occur at intervals of not less than 24 hours and in dosage increments of 1 mg per day. Risperidone can be administered in flexible doses over a range of 1 to 6 mg per day to optimise each patient's level of efficacy and tolerability. Daily doses over 6 mg risperidone have not been investigated in patients with manic episodes.

For the treatment of conduct disorder
The dose will depend on your child's weight:

For children who weigh less than 50 kg

- The starting dose will normally be 0.25 mg (0.25 ml of RISPERDAL® oral solution 1 mg/ml) once a day
- The dose may be increased every other day in steps of 0.25 mg per day
- The usual maintenance dose is 0.25 mg to 0.75 mg (0.25 ml to 0.75 ml of RISPERDAL® oral solution 1 mg/ml) once a day.

For children who weigh 50 kg or more

- The starting dose will normally be 0.5 mg (0.5 ml of RISPERDAL® oral solution 1 mg/ml) once a day
- The dose may be increased every other day in steps of 0.5 mg per day
- The usual maintenance dose is 0.5 mg to 1.5 mg once a day.

The oral solution is the recommended form to administer 0.5 mg dose.

Treatment duration in patients with conduct disorder should be not more than 6 weeks.

Children under 5 years old should not be treated with RISPERDAL® for conduct disorder.

For people with reduced or weakened kidney or liver function

Your doctor will tell you how many tablets or how much solution is appropriate to your particular situation.

- When to use it

Always take RISPERDAL® exactly as your doctor has told you. You should check with your doctor if you are not sure.

- How long to use it

Continue taking RISPERDAL® for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as possible instead of your next dose.

If it is almost time for your next dose, do not take the missed dose but take your next dose as usual and continue your course.

Important note: never take more than 16 mg per day.

- If you use too much (overdose)

In overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medications together with RISPERDAL®. If you experience the above signs, please contact your doctor.

In the meantime, you can always start treating these disturbances with activated charcoal, which absorbs any medicine still in the stomach.

While you are using it

- Things you must do

Oral Tablets for Swallowing

There are two kinds of oral tablets for swallowing, each containing a different amount of medically active substance. You can identify the strength by the color and shape of the tablets. This is explained in “Product Description”.

Drinkable Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The solution comes with a syringe (pipette), with which you can obtain the exact amount from the bottle. Use only the syringe (pipette) delivered with this medicine for measuring the dose prescribed by your doctor.

Directions for opening the bottle and using the pipette:

Dispensing Diagram

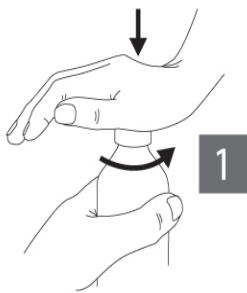


Fig. 1: The bottle comes with a child-proof cap and should be opened as follows:

- Push the plastic screw cap down while turning it counter-clockwise.
- Remove the unscrewed cap.

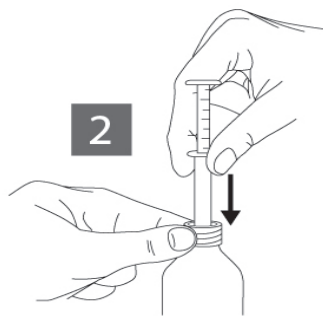


Fig. 2: Insert the pipette into the bottle.

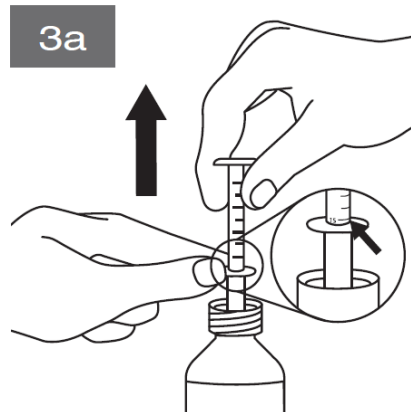
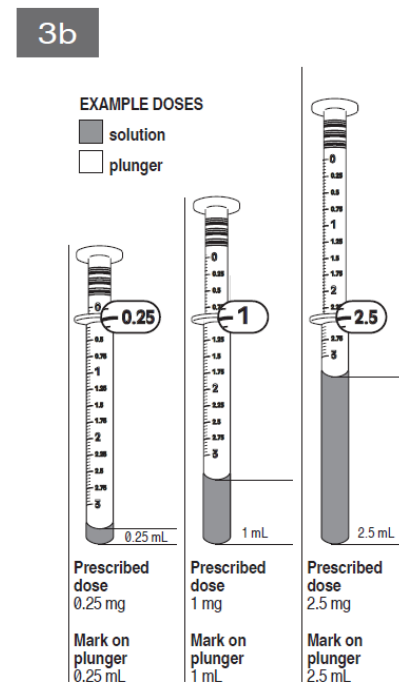


Fig. 3: While holding the bottom ring (Fig 3a), pull the top ring up to the mark that corresponds to the number of milliliters or milligrams you need to give (See examples Fig 3b).



Measure the exact dose of medicine you need. Pay attention when measuring a small dose. For example, for 0.25 mg measure, 0.25 ml (a quarter milliliter); for 0.5 mg, measure 0.5 ml (half a milliliter).

1 ml of RISPERDAL® oral solution contains 1 mg risperidone. The measured volume is printed every 0.25 ml / 0.25 mg on the plunger.

Fig 3b shows **examples** of prescribed doses and corresponding marks on the plunger.



Fig. 4: Holding the bottom ring, remove the entire pipette from the bottle. Empty the pipette into any nonalcoholic drink, except for tea, by sliding the upper ring down. Close the bottle. Rinse the pipette with some water and let it air dry.

- Things you must not do

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

In elderly with dementia, sudden change in mental state or sudden weakness or numbness of the face, arms or legs, especially on one side, or instances of slurred speech have been seen. If any of these should occur, even for a short period of time, seek medical attention right away.

- Things to be careful of
Weight Gain

Try to eat moderately, since RISPERDAL® could induce weight gain.

Driving or using machines

RISPERDAL® might affect your alertness or driving ability. You are therefore advised not to drive or to operate machines before your doctor has assessed your personal sensitivity to RISPERDAL®.

Side effects

Like all medicines, RISPERDAL® can cause side effects. Listed below are adverse reactions related to RISPERDAL®

treatment. Should you experience these symptoms, please consult your doctor.

Very Common (in more than 1 in 10 people)

- Difficulty falling or staying asleep;
- Parkinsonism: This condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles;
- Feeling sleepy, or less alert.

Common (in more than 1 in 100 people but less than 1 in 10 people)

- Sinus infection, Urinary tract infection;
- Sleep disorder, Anxiety, Restlessness;
- Dystonia: sustained involuntary contraction of muscles;
- Dizziness;
- Dyskinesia: involuntary muscle movements;
- Tremor (shaking);
- Blurry vision;
- Rapid heart rate, High blood pressure, Shortness of breath;
- Sore throat, Cough, Nosebleeds, Stuffy nose;
- Abdominal pain or discomfort, Vomiting, Nausea, Constipation, Diarrhea,
- Indigestion, Dry mouth;
- Rash;
- Incontinence (lack of control) of urine;
- Swelling of the body, arms or legs, Fever, Weakness, Fatigue (tiredness), Pain;
- Fall.

Elderly

- Lung infection;
- Decreased appetite;
- "Pink eye"
- Skin redness

Talk to your doctor or pharmacist if you experience:

- Increases in blood sugar level and/or symptoms of high blood sugar (e.g. increased thirst, increased hunger, and frequent urination)
- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during sleep (sleep apnoea)

- Difficulty or inability to pass urine (urinary retention)

During a long treatment, RISPERDAL® might cause involuntary twitching in the face. Should this happen, consult your doctor.

Very rarely a state of confusion, reduced consciousness, high fever, or stiff muscles might occur. If this happens, contact a doctor right away and tell him or her that you are taking RISPERDAL®.

In very rare cases, high blood sugar has been reported. Contact your doctor if you experience symptoms, such as excessive thirst or urination.

There are other possible side effects of RISPERDAL®. For more information, ask your doctor or pharmacist.

It should be emphasized, though, that most people will not have any such problems. However, do not hesitate to report any undesired effects to your doctor or pharmacist. Further, if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccine (AEFI))

Storage and disposal of RISPERDAL®

- *Storage*
Keep RISPERDAL® below 30°C. Protect the solution from freezing.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

The letters "EXP" on the packaging means that the medicine cannot be kept indefinitely.

Therefore, you should not use RISPERDAL® beyond the date printed after "EXP" (month and year), even if it has been stored properly.

Keep all medicines out of the reach of children.

- *Disposal*
You are advised to return old medicines to your pharmacist.

Make a habit of returning unused or old medicines to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- *What it looks like*
Tablets
There are two types of oral tablets for swallowing, each containing a different amount of risperidone:
 - white, film coated half-scored oblong biconvex tablets containing 1 mg of risperidone (marked JANSSEN and RIS 1);
 - orange, film coated half-scored oblong biconvex tablets containing 2 mg of risperidone (marked JANSSEN and RIS 2);

Drinkable Solution

The drinkable solution comes as a 30 ml and 100 ml bottle, both with a pipette.

When full, the pipette supplied with the 30 ml and 100 ml bottle contains 3 milliliters drinkable solution, which corresponds to 3 milligrams of risperidone (1 milliliter contains 1 milligram).

The smallest amount you can take is 0.25 milliliter, which contains 0.25 milligram of risperidone.

- *Ingredients*
 - Active ingredient
The actual medicine in RISPERDAL® is risperidone.

- Inactive ingredients

Tablets

The oral tablets also contain: lactose monohydrate, maize starch, microcrystalline cellulose, hypromellose 2910 15 mPa.s, magnesium stearate, colloidal anhydrous silica, sodium lauryl sulfate.

The 2 mg tablet also contains talc, titanium dioxide and orange yellow S aluminum lake.

Drinkable solution

The solution also contains tartaric acid, benzoic acid, sodium hydroxide and purified water.

- MAL numbers

RISPERDAL[®] 1 mg, 2 mg:

MAL20002242AZ

MAL20002243AZ

RISPERDAL[®] oral solution:

MAL19992548AZ

Not all pack sizes may be marketed.

Manufacturer

RISPERDAL[®] tablets 1, 2 mg:

Janssen-Cilag S.p.A

Via C. Janssen,

Borgo S. Michele, 04100 Latina, Italy

RISPERDAL[®] oral solution:

Janssen Pharmaceutica N.V.

Turnhoutseweg 30

B – 2340 Beerse, Belgium

Product registration holder

Johnson & Johnson Sdn Bhd (3718-D)

Level 8, The Pinnacle,

Persiaran Lagoon, Bandar Sunway,

46150, Petaling Jaya, Selangor, Malaysia

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