RISPERDAL®

Tablets; Oral Solution

Risperidone

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some of the common questions about Risperdal. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about using Risperdal, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with your medicine.

You may need to read it again.

What RISPERDAL is used for

Risperdal belongs to a group of medicines called antipsychotic agents which improve the symptoms of certain types of mental illness.

It is used for:

- treatment of sudden (acute) and long-term (chronic) schizophrenia and other types of related psychoses. These are disorders related to thought, feeling and/or action.
- short term treatment of acute mania associated with bipolar 1 disorder. This condition is characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility or poor judgement including disruptive or aggressive behaviours
- treatment of behavioural problems in Alzheimer patients with a decline in mental ability (dementia). These problems include: aggression through words or action, morbid suspiciousness, agitation or wandering
- treatment of conduct and other disruptive behaviours such as aggression, impulsiveness and self-injury in children (over 5 years old), adolescents and adults who are intellectually disabled.
- treatment of behavioural symptoms of autism in children and adolescent

Risperdal helps to correct a chemical imbalance in the brain associated with these conditions.

This medicine has been approved for the uses mentioned above. However, your doctor may prescribe it for another use. If you want more information, ask your doctor. It is only available with a doctor's prescription.

Risperdal is not addictive.

Before you use RISPERDAL

When you must not use it

Do not use RISPERDAL:

- if you know you are allergic to any of its ingredients (signs of allergy include skin rash, itching, shortness of breath, and/or swollen face - see the last section of this leaflet for a list of ingredients)
- if the packaging is torn or shows signs of being tampered with
- if the tablets or the oral solution do not look right
- to treat any other complaints unless your doctor says it is safe to do so.

Before you start to use it

RISPERDAL should be used with caution in some patients.

Tell your doctor if you have or have ever had any medical conditions, especially the following:

- heart or blood vessel problems, including high and low blood pressure.

  Low blood pressure can result from using RISPERDAL together with medications to treat high blood pressure. So, if you need to use both RISPERDAL and medications to reduce blood pressure, consult your doctor.

  RISPERDAL should be used with caution, and only after consultation with your doctor, if you have heart problems, particularly irregular heart rhythm, abnormalities in electrical activity of the heart, or if using medications that can change the heart's electrical activity.
- disease of the blood vessels of the brain including stroke
- dehydration
- kidney or liver problems
- Parkinson's disease
- dementia or Lewy body dementia
- epilepsy, seizures
- restlessness or difficulty sitting still
- intraoperative iris syndrome (a complication that may occur during cataract extraction)

- low blood potassium levels (hypokalaemia)
- low blood sugar
- breast cancer
- disease of the pituitary gland
- diabetes
- Tardive dyskinesia (a reaction to some medicines with uncontrollable twitching or jerking movements of the arms and legs)
- Neuroleptic Malignant Syndrome (a serious reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions).
- blood clots

  Tell your doctor if you or someone else in your family has a history of blood clots. Blood clots in the lungs and legs have been seen in patients taking RISPERDAL. Blood clots in the lungs can be fatal.
- low white blood cell count

  As dangerously low numbers of certain types of white blood cells needed to fight infection in your blood has been seen very rarely with patients taking RISPERDAL, your doctor may check your white blood cell counts. Tell your doctor if 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).

Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will advise you whether or not you should take RISPERDAL.

Shaking, muscle stiffness and difficulty in feeding, all of which are reversible, may occur in newborns, if a mother uses the medicine in the last trimester of her pregnancy

Tell your doctor if you are breast-feeding.

RISPERDAL is excreted in breast milk. It is recommended that you do not breast-feed while taking the medicine.

Taking other medicines

RISPERDAL can increase the effect of other medicines which slow your reactions.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Ask your doctor or pharmacist before taking any other medicines. RISPERDAL can increase the effects of medicines which slow your reactions. These include herbal treatments and those bought in a pharmacy or supermarket.

Tell your doctor if you are taking:

- diuretics like frusemide, a drug used to treat high blood pressure, or to treat swelling of parts of the body caused by the build-up of too much fluid.There is an increased risk of side effects or death in elderly people if frusemide is also taken with RISPERDAL.
- sleeping tablets, tranquillisers, pain-killers, antihistamines
- carbamazepine, a drug mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face) may decrease the level of RISPERDAL in your blood.
- medicines to treat Parkinson's disease or a tremor
- medicines to treat epilepsy
- medicines to treat depression, panic disorder, anxiety or obsessive-compulsive disorder. For example fluoxetine and paroxetine may increase the level of RISPERDAL in your blood. So tell your doctor if you start and/or stop taking fluoxetine or paroxetine.
- medicines for your heart or blood pressure
- medicines used to treat bacterial and fungal infection
- medicines to treat pre-menstrual dysphoric disorder
- other medicines to treat mental illness or psychotic conditions
- medicines to relieve severe nausea and vomiting.

Using RISPERDAL

How much to take

Your doctor will decide the dose suitable for you.

Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting your doctor first.

Important note: never take more tablets or solution than your doctor tells you to take.

The maximum daily dose of RISPERDAL is 5 milligrams taken twice a day. Check with your doctor if more than this has been prescribed. The effects of high doses are not yet known.

RISPERDAL cannot be recommended for use in children with schizophrenia under 15 years at the present time as there is little experience with the product in this group.

For Schizophrenia and Related Psychoses

The usual starting dose of RISPERDAL is 1 mg twice a day. This will be gradually increased by your doctor to suit your needs.

From then on, the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 4 to 6 milligrams per day is usually sufficient but your doctor will determine the dose most suitable for you.

For Elderly Patients with Schizophrenia or Related Psychoses

For older patients a starting dose of 0.5 mg (or 0.5 mL of solution) twice a day (in the morning and in the evening is usual). The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

Patients with impaired kidney and liver function.

If you have kidney or liver disease a starting dose of 0.5 mg (or 0.5 mL of solution) twice a day (in the morning and in the evening) is usual. The dose may be increased by 0.5 mg twice daily to 1 to 2 mg twice a day (in the morning and in the evening).

For acute mania

The recommended starting dose is 2mg once a day. This dose can be adjusted by dose increases of 1mg when needed every 24 hours. Most people feel better with doses between 2mg and 6mg a day. Your doctor may decide you should take another drug called a mood stabiliser as well as RISPERDAL.

For Behavioural Problems in People with Dementia

The usual starting dose is 0.25 mg twice daily. This may be gradually increased by your doctor to suit your needs.

From then on the dose can be taken once a day or twice a day according to your doctor's instructions. For long-term treatment, 1 mg daily is the usual dose but your doctor will determine the dose most suitable for you.

For Disruptive Behaviour Disorders in Adults and Children

For people who weigh 50 kg or more, the usual starting dose is 0.5 mg (or 0.5 mL of solution) once a day. The dose may be increased by 0.5 mg once every two days, to the usual dose of 0.5 to 1.5 mg once a day.

For people who weigh less than 50 kg, the usual starting dose is 0.25 mg once a day. The dose may be increased by 0.25 mg once every two days, to the usual dose of 0.25 to 0.75 mg once a day.

Your doctor will advise you on how much RISPERDAL you need.

RISPERDAL cannot be recommended for use in children with disruptive behaviour disorders under 5 years at the present time as there is little experience with the product in this group.

For Behavioural Disorders Associated with Autism in Children and Adolescents

For people weighing less than 20kg the usual starting dose is 0.25mg. On day 4 this dose can be increased to 0.5mg.

For people weighing 20kg or more the usual starting dose is 0.5mg. On day 4 this dose can be increased to 1.0mg.

Response should be assessed at day 14; only in patients not achieving sufficient clinical response should additional dose increases be considered. Your doctor will advise you on how much RISPERDAL you need. When trialled, the maximum dose in patients with autism did not exceed 1.5mg/day in patients less than 20kg, 2.5mg in patients 20kg or more, or 3.5mg in patients more than 45kg

When to take it

RISPERDAL may be taken as a single dose, once a day or it may be taken in divided doses twice a day (in the morning and in the evening). You may take RISPERDAL either with or between meals.

How to take it

Swallow RISPERDAL tablets with water or other liquid.

Mix RISPERDAL oral solution with a non-alcoholic drink.

Mineral water, orange juice, coffee and milk are suitable. Do not use tea.

It is very important that you take the correct amount of RISPERDAL, but this will vary from person to person. Your doctor will adjust the number and strength of the tablets or the amount of solution until the desired effect is obtained.

How to use

Directions for opening the bottle and using the pipette for RISPERDAL Oral Solution

Step 1:

The bottle comes with a child-resistant cap.

To open, push the screw cap down while turning it anti-clockwise. Remove the unscrewed cap.

Step 2:

Use the pipette from the container. While holding the bottom ring, pull the top ring up to the mark that corresponds to the dose you need.

Step 3:

Holding the bottom ring, remove the entire pipette from the bottle.

Step 4:

Empty the contents of the pipette into a non-alcoholic drink by sliding the upper ring down. Mineral water, orange juice, coffee and milk are suitable. Do not use tea.

Step 5:

Rinse and dry the pipette after use and store it in its case. Close the bottle.

How long to take it

Continue taking the tablets for as long as your doctor tells you.

RISPERDAL helps control your condition, but does not cure it. Therefore you must take RISPERDAL every day.

Do not stop taking it unless your doctor tells you to - even if you feel better.

If you forget to take RISPERDAL

- If you forget to take RISPERDAL, take the missed dose as soon as you remember instead of your next dose. Then go back to taking it as you would normally.

- Do not take a double dose to make up for the one you missed.
- If you forget to take RISPERDAL for 5 days or more, tell your doctor before starting your medicine again.

If you have problems remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much

Immediately telephone your doctor or the Poisons Information Centre, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much RISPERDAL. Do this even if there are no signs of discomfort or poisoning.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

Signs of overdose may include drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, increased heart rate, very low blood pressure causing fainting or unconsciousness.

While you are using RISPERDAL

Things you must do

Always follow your doctor's instructions carefully, and seek your doctor's advice before changing or stopping treatment.

Your doctor will be happy to discuss any questions you may have with your treatment.

Try to eat a moderate diet.

RISPERDAL can cause weight gain.

You should make sure you are not pregnant.

Pre-menopausal women should tell their doctor if they do not have a period for more than six months while taking RISPERDAL.

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking antipsychotic medicines, including RISPERDAL. This condition is more likely to occur during long term treatment with RISPERDAL, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking RISPERDAL.

Try to drink plenty of water, especially if you are elderly and taking frusemide (a diuretic). This will help decrease your risk of certain side effects.

Things you must not do

Do not drink alcohol.

RISPERDAL can increase the effects of alcohol.

Things to be careful of

Be careful driving or operating machinery until you know how RISPERDAL affects you.

RISPERDAL may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to RISPERDAL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

Avoid excessive eating, as there is a possibility of weight gain when taking RISPERDAL.

Side Effects

All medicines can have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RISPERDAL

You may need medical treatment if you get some of the side effects.

Taking it for the first time.

At the start of treatment you may have a fall in blood pressure making you feel dizzy on standing up, or your heart may beat faster. These should go away after a few days. Tell your doctor if they continue or worry you.

Tell your doctor if you notice any of the following and they worry you:

- **difficulty thinking or working because of:**
- sleeplessness
- headache
- trembling
- drowsiness, tiredness, difficulty in concentrating
- **behavioural changes such as:**
- agitation
- anxiety
- **joint or movement changes such as:**
- muscle stiffness or pain, bone or muscle ache
- joint stiffness or swelling
- restlessness in the legs
- change in gait

- **other changes such as:**
- weight gain
- increased or decreased appetite
- indigestion, nausea, abdominal pain, constipation, diarrhoea
- excessive thirst
- dry mouth
- frequent urination, incontinence
- inability to or pain when passing urine
- unusual secretion of breast milk
- breast swelling
- missed or irregular menstrual periods
- involuntary movements of the tongue, face, mouth, jaws, arms, legs or trunk
- pneumonia, infection
- blurry vision, eye rolling, involuntary movement of the eyes
- "flu-like" symptoms, vomiting, toothache
- nosebleeds
- sexual dysfunction , priapism (prolonged erection)
- vertigo
- hardening of the skin
- lack of emotion, elated mood

These are mild side effects of RISPERDAL but may require medical attention.

- **Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following: heart or blood pressure problems such as:**
- fall in blood pressure, particularly on standing. This will be apparent to you as light-headedness or dizziness that passes after a few seconds or after sitting down again
- faster heart rate, slowed heart rate, heart beat irregularities
- **body temperature changes such as:**
- fever
- abnormally high body temperature

These may be serious side effects of RISPERDAL. You may need urgent medical attention.

Serious side effects are uncommon.

If any of the following happen, stop taking RISPERDAL and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body. If you have them, you may have had a serious allergic reaction to RISPERDAL.
- sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech (these are called mini-strokes)
- low level or loss of consciousness
- in elderly patients with dementia, occurrence of following even for a short period time: sudden weakness or numbness of the face, arms or legs, especially on one side, instances of slurred speech and stroke

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some consumers.

Do not hesitate to report any other side effects to your doctor or pharmacist.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using RISPERDAL

Storage

Keep RISPERDAL tablets in a dry place where the temperature stays below 25°C.

Keep RISPERDAL oral solution below 30°C. The oral solution should not be refrigerated.

- Do not store it or any medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.
- Do not use RISPERDAL beyond the date (month and year) printed on the pack after the letters "EXP", even if it has been stored properly. Medicines cannot be stored indefinitely.
- Do not use RISPERDAL if the appearance of the tablets or oral solution has changed.

Disposal

If your doctor tells you to stop taking RISPERDAL or if it has passed the expiry date, ask your pharmacist what to do with any that are left over.

Product Description

What it looks like

RISPERDAL Tablets

You can identify RISPERDAL Tablets by their colour and shape. This is important because there are 5 types of RISPERDAL, each containing a different amount of risperidone:

- 0.5 mg brownish red, oblong biconvex grooved tablets marked with "Ris 0.5" on the grooved

side and "JANSSEN" on the other side.

- 1 mg white, oblong grooved tablets marked "Ris 1" on the grooved side.
- 2 mg orange, oblong grooved tablets marked "Ris 2" on the grooved side.
- 3 mg yellow, oblong grooved tablets marked "Ris 3" on the grooved side.
- 4 mg green, oblong grooved tablets marked "Ris 4" on the grooved side.

All strengths come in boxes of 60 tablets, except the 0.5 mg which comes in a box of 20 tablets.

RISPERDAL oral solution

RISPERDAL oral solution is a clear, colourless solution. It is packed in an amber bottle (30 or 100mL) with a pipette which measures the dose in milligrams (mg) and millilitres (mL). One full pipette contains 3 mL (or 3 mg) of oral solution. The smallest amount you can measure with the pipette is 0.25 mL.

Ingredients

The active ingredient in RISPERDAL is risperidone.

RISPERDAL Tablets

RISPERDAL tablets contain either 0.5, 1, 2, 3 or 4 mg (milligrams) of risperidone. The tablets also contain lactose, maize starch, microcrystalline cellulose, hypromellose, magnesium stearate, colloidal anhydrous silica, sodium lauryl sulphate, propylene glycol.

The 0.5 mg tablets also contain titanium dioxide, purified talc and red iron oxide.

The 2 mg tablets also contain titanium dioxide, purified talc and sunset yellow (CI 15985).

The 3 mg tablets also contain titanium dioxide, purified talc and quinoline yellow (CI 47005).

The 4 mg tablets also contain titanium dioxide, purified talc, quinoline yellow (CI 47005) and indigo carmine (CI 73015).

RISPERDAL oral solution

The RISPERDAL oral solution contains 1 mg/mL of risperidone, as well as tartaric acid, benzoic acid, sodium hydroxide and purified water.

Sponsor

Janssen-Cilag Pty Ltd

1-5 Khartoum Road North Ryde NSW 2113

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

Registration Numbers

0.5mg Tablet - AUST R 71849

1 mg Tablet - AUST R 47008

2 mg Tablet - AUST R 48486

3 mg Tablet - AUST R 47010

4 mg Tablet - AUST R 47011

1 mg/mL Oral Solution - AUST R 56444

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