

PACKAGE LEAFLET: INFORMATION FOR THE USER

- Risperidone 0.5 mg film-coated tablets**
- Risperidone 1 mg film-coated tablets**
- Risperidone 2 mg film-coated tablets**
- Risperidone 3 mg film-coated tablets**
- Risperidone 4 mg film-coated tablets**
- Risperidone 6 mg film-coated tablets**

Risperidone

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What Risperidone is and what it is used for
- Before you take Risperidone
- How to take Risperidone
- Possible side effects
- How to store Risperidone
- Further information

1. WHAT RISPERIDONE IS AND WHAT IT IS USED FOR

Risperidone belongs to a group of medicines called ‘anti-psychotics’.

Risperidone is used to treat the following:

- Schizophrenia, where you may see, hear or feel things that are not there, believe things that are not true or feel unusually suspicious, or confused
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called “bipolar disorder”
- Short-term treatment (up to 6 weeks) of long-term aggression in people with Alzheimer’s dementia, who harm themselves or others. Alternative (non-drug) treatments should have been used previously
- 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.

2. BEFORE YOU TAKE RISPERIDONE

Do not take Risperidone if:

- You are allergic (hypersensitive) to risperidone or any of the other ingredients of Risperidone (listed in Section 6 below).
- If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Risperidone. Risperidone may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight. As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking Risperidone, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly.

Take special care with Risperidone
Check with your doctor or pharmacist before taking Risperidone if:

- You have a heart problem. Examples include an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure. Risperidone may cause low blood pressure. Your dose may need to be adjusted
- You know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- You have ever experienced involuntary movements of the tongue, mouth and face
- You have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- You have Parkinson’s disease or dementia
- You are diabetic
- You have epilepsy
- You are a man and you have ever had a prolonged or painful erection.
- You have problems controlling your body temperature or overheating
- You have kidney problems
- You have liver problems
- You have an abnormally high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin
- You or someone else in your family has a history of blood clots, as antipsychotics have been associated with formation of blood clots.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperidone.

Risperidone may cause you to gain weight.

Elderly people with dementia
In elderly patients with dementia, there is an increased risk of stroke. You should not take risperidone if you have dementia caused by stroke.

During treatment with risperidone you should frequently see your doctor.

Medical treatment should be sought straight away if you or your care-giver notice a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke.

Children and adolescents
Before treatment is started for conduct disorder, other causes of aggressive behaviour should have been ruled out.

If during treatment with risperidone tiredness occurs, a change in the time of administration might improve attention difficulties.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

It is especially important to talk to your doctor or pharmacist if you are taking any of the following:

- Medicines that work on your brain such as to help you calm down (benzodiazepines) or some medicines for pain (opiates), medicines for allergy (some antihistamines), as risperidone may increase the sedative effect of all of these
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat

- Medicines that cause low blood potassium (eg. certain diuretics)
- Medicines to treat raised blood pressure. Risperidone can lower blood pressure
- Medicines for Parkinson’s disease (such as levodopa)
- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build up of too much fluid (such as furosemide or chlorothiazide). Risperidone taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

The following medicines may reduce the effect of risperidone

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin (medicines for epilepsy)
- Phenobarbital

If you start or stop taking such medicines you may need a different dose of risperidone.

The following medicines may increase the effect of risperidone

- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazines (eg. used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)

If you start or stop taking such medicines you may need a different dose of risperidone.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperidone.

Taking Risperidone with food and drink
You can take this medicine with or without food. You should avoid drinking alcohol when taking Risperidone.

Pregnancy and breast-feeding

- Talk to your doctor before using Risperidone if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you can take it
- The following symptoms may occur in newborn babies, of mothers that have used risperidone in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Dizziness, tiredness, and vision problems may occur during treatment with Risperidone. Do not drive or use any tools or machines without talking to your doctor first.

Important information about some of the ingredients of Risperidone

Risperidone tablets contain lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. The 2 mg and 6 mg Risperidone tablets contain a colour called **Orange Yellow S (E110)**. E110 may cause allergic reactions. This allergy is more common in those people who are allergic to aspirin.

3. HOW TO TAKE RISPERIDONE

Always take Risperidone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For the treatment of schizophrenia

- Adults**
 - The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day
 - Your dose may then be adjusted by your doctor depending on how you respond to the treatment
 - Most people feel better with daily doses of 4 to 6 mg
 - This total daily dose can be divided into either one or two doses a day. Your doctor will tell you which is the best for you.

- Elderly people**
 - Your starting dose will normally be 0.5 mg twice a day
 - Your dose may then be gradually increased by your doctor to 1 mg to 2 mg twice a day
 - Your doctor will tell you which is the best for you.

Children and adolescents
Children and adolescents under 18 years old should not be treated with Risperidone for schizophrenia.

For the treatment of mania

- Adults**
 - Your starting dose will usually be 2 mg once a day
 - Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
 - Most people feel better with doses of 1 to 6 mg once a day.

- Elderly people**
 - Your starting dose will usually be 0.5 mg twice a day
 - Your dose may then be gradually adjusted by your doctor to 1 mg to 2 mg twice a day depending on how much you respond to the treatment.

Children and adolescents
Children and adolescents under 18 years old should not be treated with Risperidone for mania.

For the treatment of long-standing aggression in people with Alzheimer’s dementia

- Adults (including elderly people)**
 - Your starting dose will normally be 0.25 mg twice a day
 - Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment
 - Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day
 - Treatment duration in patients with Alzheimer’s dementia should be not more than 6 weeks.

For the treatment of conduct disorder in children and adolescents

- 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 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 once a day.

- For children who weigh 50 kg or more
 - The starting dose will normally be 0.5 mg 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.

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

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

People with kidney or liver problems

Regardless of the disease to be treated, all starting doses and following doses of risperidone should be halved. Dose increases should be slower in these patients.

Risperidone should be used with caution in this patient group.

How to take Risperidone

Always take Risperidone exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how much medicine to take and for how long. This will depend on your condition and varies from person to person. The amount of medicine you should take is explained under the “How much to take” sub-heading.

You should swallow your tablet with a drink of water

If you take more Risperidone than you should
See a doctor right away. Take the medicine pack with you

In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits.

If you forget to take Risperidone
If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual. If you miss two or more doses, contact your doctor.

Do not take a double dose (two doses at the same time) to make up for a forgotten dose

If you stop taking Risperidone
You should not stop taking this medicine unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop this medicine, your dose may be decreased gradually over a few days. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Risperidone can cause side effects, although not everybody gets them.

Tell your doctor immediately if you:

- Experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately.
- Have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a stroke
- Experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed
- Are a man and experience prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed
- Experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed

Tell your doctor immediately if you experience any of the side effects above.

The following side effects may happen:

- Very Common** (affects more than 1 user in 10):
 - Parkinsonism. This is a medical term that includes many symptoms. Each individual symptom may occur less frequently than in 1 in 10 people. Parkinsonism includes: increase in saliva secretion or watery mouth, musculoskeletal stiffness, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression on the face, muscle tightness, stiff neck, muscle stiffness, small, shuffling, hurried steps and lack of normal arm movements when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex)
 - Headache, difficulty falling or staying asleep.
- Common** (affects 1 to 10 users in 100):
 - Drowsiness, fatigue, restlessness, inability to sit still, irritability, anxiety, sleepiness, dizziness, poor attention, feeling exhausted, sleep disorder
 - Vomiting, diarrhoea, constipation, nausea, increased appetite, abdominal pain or discomfort, sore throat, dry mouth
 - Weight increased, increase in body temperature, decreased appetite
 - Difficulty breathing, lung infection (pneumonia), flu, infection of the breathing passages, blurred vision, nose congestion, nose bleeding, cough
 - Urinary tract infection, bed wetting
 - Tremor, Muscle spasm, involuntary movements of face or arms and legs, joint pain, back pain, swelling of arms and legs, pain in arms and legs
 - Rash, skin redness
 - Fast beating heart, chest pain
 - Blood prolactin hormone level increased.

Uncommon (affects 1 to 10 users in 1000):

- Excessive drinking of water, stool incontinence, thirst, very hard faeces, hoarseness or voice disorder
- Lung infection caused by inhaling of food into the breathing passages, bladder infection, “pink eye”, sinus infection, viral infection, ear infection, tonsil infection, infection under the skin, eye infection, stomach infection, eye discharge, yeast infection of nails
- Abnormal electrical conduction of the heart, drop in blood pressure after standing, low blood pressure, feeling dizzy after changing body position, abnormal results from test that records electric activity of the heart (ECG), abnormal heart rhythm, awareness of heart beating, heart rate increased or decreased
- Loss of bladder control (Urinary incontinence), pain when passing urine, frequent passing of urine
- Confusion, disturbance in attention, low level of consciousness, excessive sleep, nervousness, elated mood (mania), lack of energy and interest
- Liver enzymes increased, white blood cell count decreased, low haemoglobin or red blood cell count (anaemia), increase in eosinophils (special white blood cells), blood creatinine phosphokinase increased, decrease in platelets (blood cells that help you stop bleeding)
- Muscle weakness, muscle pain, ear pain, neck pain, joint swelling, abnormal posture, joint stiffness, musculoskeletal chest pain, chest discomfort
- Skin lesion, skin disorder, dry skin, intense itching of skin, acne, hair loss, skin inflammation caused

by mites, skin discolouration, thickening of skin, flushing, reduced skin sensitivity to pain or touch, inflammation of oily skin

- No menstruation, sexual dysfunction, erectile dysfunction, ejaculation disorder, breast discharge, enlargement of breast in men, decreased sexual drive, irregular menstruation, vaginal discharge
- Fainting, gait disturbance, sluggishness, decreased appetite resulting in malnutrition and low body weight, feeling “out of sorts”, balance disorder, allergy, oedema, speech disorder, chills, abnormal coordination
- Painful oversensitivity to light, increased blood flow to the eye, eye swelling, dry eye, increase in tears
- Breathing passage disorder, lung congestion, crackly lung noise, congestion of breathing passages, trouble speaking, difficulty swallowing, cough with sputum, coarse/whistling sound during breathing, flu-like illness, sinus congestion
- Unresponsive to stimuli, loss of consciousness, sudden swelling of lips and eyes along with difficulty breathing, sudden weakness or numbness of the face, arms, or legs, especially on one side, or instances of slurred speech that last for less than 24 hours (these are called mini-strokes or strokes), involuntary movements of face, arms, or legs, ringing in ears, face oedema
- Inability to urinate or incomplete emptying of the bladder.

Rare (affects 1 to 10 users in 10,000):

- Inability to reach orgasm, menstrual disorder
- Dandruff
- Medicine allergy, coldness in arms and legs, lip swelling, lip inflammation
- Glaucoma, reduced visual clarity, eyelid margin crusting, eye rolling
- Lack of emotion
- Change in consciousness with increased body temperature and twitching of muscles, oedema all over the body, drug withdrawal syndrome, decreased body temperature
- Fast shallow breathing, trouble breathing during sleep, chronic otitis media
- Obstruction of intestine.
- Reduced blood flow to the brain
- Decrease in white blood cells, inappropriate secretion of a hormone that controls urine volume
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis), movement disorder
- Coma due to uncontrolled diabetes
- Yellowing of the skin and the eyes (jaundice)
- Inflammation of the pancreas.
- Low blood sugar

Very rare (affects less than 1 user in 10,000):

- Life threatening complications of uncontrolled diabetes.

Unknown frequency of occurrence (frequency cannot be estimated from the available data):

- Severe allergic reaction resulting in difficulty in breathing and shock
- No granulocytes (a type of white blood cell to help you against infection)
- Prolonged and painful erection
- Dangerously excessive intake of water.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RISPERIDONE

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

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.

6. FURTHER INFORMATION

What Risperidone contains

- The active substance is risperidone. Each Risperidone film-coated tablet contains either 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg or 6 mg of risperidone.
- The other ingredients are: **Tablet core:**Lactose monohydrate, Maize starch, Magnesium stearate, Sodium laurilsulphate, Hypromellose, Cellulose, microcrystalline, Colloidal anhydrous silica. **Film-coat:** Propylene glycol, Hypromellose, Titanium dioxide (E 171), Talc.

The tablets also contain:
0.5 mg: Red Ferric Oxide (E172)
2 mg: Orange yellow S (E110)
3 mg: Quinoline yellow (E104)
4 mg: Quinoline yellow (E104) , Indigo Carmine (E132)
6 mg: Quinoline yellow (E104) , Orange yellow S (E110).

Additionally the imprint of the 6 mg tablets consists of Opacode S-1-16530 brown ink containing: Shellac glaze, Ethanol, N-Butyl-alcohol, Isopropyl alcohol, Iron oxide black (E172), Iron oxide red (E172), Iron oxide yellow (E 172), Ammonium hydroxide

What Risperidone looks like and contents of the pack

Risperidone is available in blister strips in cartons containing the following:

- 0.5 mg tablet (brownish-red, circular) 20 tablets
- 1 mg tablet (white, biconvex, oblong, break line on one side) 20, 60 tablets
- 2 mg tablet (pale orange, biconvex, oblong, break line on one side) 60 tablets
- 3 mg tablet (light yellow, biconvex, oblong, break line on one side) 60 tablets
- 4 mg tablet (green, biconvex, oblong, break line on one side) 60 tablets
- 6 mg tablet (yellow, biconvex, oblong, break line on one side and imprinted with “6” on the other side) 60 tablets

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This leaflet was last approved in 07/2015.

Colour Black

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