

Package leaflet: Information for the patient

Risperidone 0.5 mg orodispersible tablets **Risperidone 1 mg orodispersible tablets** **Risperidone 2 mg orodispersible tablets** risperidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Risperidone is and what it is used for
2. What you need to know before you take Risperidone
3. How to take Risperidone
4. Possible side effects
5. How to store Risperidone
6. Contents of the pack and other information.

1. What Risperidone is and what it is used for

This medicine 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.

Risperidone can help alleviate the symptoms of your disease and stop your symptoms from coming back.

2. What you need to know before you take Risperidone

Do not take Risperidone:

- If you are allergic to risperidone or any of the other ingredients of this medicine (listed in section 6).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Risperidone:

- If you are taking furosemide (a 'water pill,' that is used to reduce the swelling and fluid retention caused by various medical problems, including heart or liver disease).
- If you have a heart problem. For example if you have an irregular heart rhythm, a weakness of the heart muscle (heart failure), have had a heart attack, if you are prone to low blood pressure or if you are taking medicines for your blood pressure. Risperidone may cause low blood pressure. Your dose may need to be adjusted.
- If you know of any factors which would favour you having a stroke, such as high blood.
- If you or someone else in your family has a history of blood clots, as medicines like this medicine have been associated with formation of blood clots.
- pressure, cardiovascular disorder or blood vessel problems in the brain.
- If you know of any factors which would favour you developing a blood clot, such as you smoke, or have smoked, or if you are likely to be immobile for a prolonged period (e.g. after surgery or illness).
- If you have, or have had, low numbers of white blood cells in the blood, especially if this has happened when you have taken other medicines.
- If you have ever experienced involuntary movements of the tongue, mouth and face.
- If 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).
- If you have Parkinson's disease (disease of the brain affecting movement like trembling, rigid posture, slow movements and a shuffling) or dementia (a general decline in all areas of mental ability like loss of memory and other mental powers), particularly dementia with Lewy bodies (abnormal aggregates of protein that develop inside nerve cells in Parkinson's disease).
- If you are diabetic, or are at risk of developing diabetes (you may have raised levels of sugar in the blood).
- If you have epilepsy.
- If you are a man and you have ever had a prolonged or painful erection.
- If you have problems controlling your body temperature, are prone to overheating, or are, or maybe, exposed to very high temperatures or strenuous exercise.
- If you are, or become during treatment, dehydrated or have a low blood volume (hypovolaemia).
- If you have low levels of potassium or magnesium in the blood.
- If you have kidney problems.
- If you have liver problems.
- If 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.

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

During treatment

Risperidone can cause changes in the number of white blood cells, which help fight infection, therefore before and during treatment your doctor may carry out blood tests.

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 or worsening of pre-existing diabetes have been seen with patients taking Risperidone, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes blood sugar (glucose) should be monitored regularly.

Risperidone commonly raises levels of a hormone called "prolactin". This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men, low sex drive, impotence, and milky secretion from the breasts (see Possible side effects). If such side effects occur, evaluation of the prolactin level in the blood is recommended.

If you are due to have surgery on your eye, tell your doctor or hospital staff that you are taking this medicine.

During an operation on the eye for cloudiness of the lens (cataract), the pupil (the black circle in the middle of your eye) may not increase in size as needed. Also, the iris (the coloured part of the eye) may become floppy during surgery and that may lead to eye damage.

Elderly people with dementia

In elderly patients with dementia, there is an increased risk of stroke or mini-stroke (also known as a transient ischaemic attack or TIA). 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, vision problems or slurred speech, even for a short period of time. These may be signs of a stroke.

Children and adolescents

Before treatment is started your or your child's body weight may be measured and it may be regularly monitored during treatment.

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.

A small and inconclusive study has reported an increase in height in children who took risperidone, but whether this is an effect of the drug or due to some other reason is not known.

Other medicines and Risperidone

Tell your doctor or pharmacist if you are taking, have recently taken, or might take 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 (quinine, mefloquine), heart rhythm problems (such as quinidine, disopyramide, procainamide, propafenone, amiodarone, sotalol), allergies (antihistamines), some antidepressants such as tricyclic antidepressants (e.g. amitriptyline) tetracyclic antidepressants (e.g. maprotiline) or other medicines for mental health problems.
- Medicines that cause low blood potassium or magnesium .
- Medicines to treat high blood pressure. Risperidone can lower blood pressure.
- Medicines for Parkinson's disease (such as levodopa).
- Paliperidone (a medicine used to treat mental problems). Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).
- 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 (commonly used in the treatment of certain types of epilepsy).

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
- Cimetidine, ranitidine (blockers of the acidity of stomach).
- Medicines known as beta blockers (used to treat high blood pressure)
- Itraconazole and ketoconazole (medicines for treating fungal infections).
- Phenothiazines (e.g. used to treat psychosis or to calm down)
- Medicines that cause a slow heart beat, such as beta blockers or verapamil (used to treat high blood pressure or angina).
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir.

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.

Risperidone with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you, or your partner, take this medicine. Your doctor will decide if you can take it.

Pregnancy

You should not take this medicine during pregnancy unless your doctor thinks that it is clearly necessary.

- 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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you, or your partner take this medicine. Your doctor will decide if you can take it.

Breast-feeding

This medicine passes into breast milk. You should not take this medicine while you are breast-feeding unless your doctor tells you to.

Fertility

Risperidone can rise your levels of a hormone called “prolactin”. This may impact fertility in both female and male patients (see section 4 “Possible side effects”)

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.

Risperidone contains aspartame (E951)

This medicine contains 2.5 mg (0.5 mg tablets), 5 mg (1 mg tablets), 10 mg (2 mg tablets), 15 mg (3 mg tablets), 20 mg (4 mg tablets) aspartame in each tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Risperidone

Always take this medicine exactly as your doctor or pharmacist has told you. 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 recommended dose is:

For the treatment of schizophrenia

Adults

- The recommended 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 dose is the best for you.

Elderly people

- Your recommended 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 dose is the best for you.

Use in 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 recommended 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 recommended 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.

Use in 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 recommended 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 from 5 to 18 years of age

The dose will depend on your child's weight:

For children who weigh less than 50 kg

- The recommended 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 recommended maintenance dose is 0.25 mg to 0.75 mg once a day.

For children who weigh 50 kg or more

- The recommended 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 recommended 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 why you are taking this medicine, 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.

Please note, the 0.25 mg starting dose cannot be achieved with Risperidone as it cannot be split in two equal halves for dosing purposes. For doses in practicable with this medicinal product other medicinal products with appropriate pharmaceutical form are available.

Route and method of administration

Risperidone orodispersible tablets should be taken orally.

Only remove a tablet from the blister when it is time to take your medicine. See diagram below.

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Peel off the backing of the blister to expose the tablet.
3. Carefully take out the tablet from the packaging. Do not push the tablet through the blister because it may break. Remove the tablet from the package with dry hands.
4. Place the tablet on your tongue straight away. Allow it to dissolve directly in your mouth.
5. Swallow it with saliva or with a drink of water if you wish.

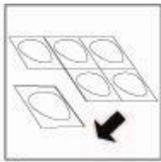


Fig. 1

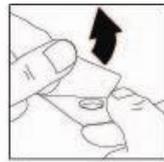


Fig. 2

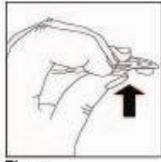


Fig. 3



Fig. 4

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 fast or abnormal heart beats 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Tell your doctor immediately or go to a hospital emergency department if you:

Uncommon side effects (may affect up to 1 in 100 people):

- 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 tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Tell your doctor immediately if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Risperidone may be needed.

Rare side effects (may affect up to 1 in 1,000 people):

- Experience a severe rash, itching or hives on the skin; swelling of the face, lips, tongue or throat, shortness of breath, difficulty in breathing, dizziness and shock. These may be signs of a severe allergic reaction or angioedema.
- 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.

- 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.

The following side effects may also happen:

Very common side effects (may affect more than 1 in 10 people):

- Difficulty falling or staying asleep.
- Parkinsonism. The condition may include: slow or impaired movement, sensation of stiffness or tightness of the muscles (making your movements jerky), and sometimes even a sensation of movement "freezing up" and then restarting. Other signs of parkinsonism include a slow shuffling walk, a tremor while at rest, increased saliva and/or drooling, and a loss of expression on the face.
- Headache, difficulty falling or staying asleep.
- Feeling sleepy, or less alert.

Common side effects (may affect up to 1 in 10 people):

- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu.
- Raised levels of a hormone called "prolactin" found in a blood test (which may or may not cause symptoms). Symptoms of high prolactin occur uncommonly and may include in men breast swelling, difficulty in getting or maintaining erections, decreased sexual desire or other sexual dysfunction. In women they may include breast discomfort, leakage of milk from the breasts, missed menstrual periods, or other problems with your cycle or fertility problems.
- Weight gain.
- Increased appetite.
- Decreased appetite.
- Sleep disorder, irritability, depression, anxiety, restlessness.
- Dystonia: This is a condition involving slow or sustained involuntary contraction of muscles. While it can involve any part of the body (and may result in abnormal posture), dystonia often involves muscles of the face, including abnormal movements of the eyes, mouth, tongue or jaw.
- Dizziness
- Dyskinesia: This is a condition involving involuntary muscle movements, and can include repetitive, spastic or writhing movements, or twitching.
- Tremor (shaking).
- Blurry vision, eye infection or "pink eye".
- Rapid heart rate.
- High blood pressure.
- Shortness of breath.
- Sore throat.
- Cough.
- Nose bleeds.
- Stuffy nose.
- Abdominal pain, abdominal discomfort, vomiting, nausea, constipation, diarrhoea, indigestion, dry mouth, toothache.
- Rash, skin redness.
- Muscle spasms, bone or muscle ache, back pain, joint pain.
- Incontinence (lack of control) of urine.
- Swelling of the body, arms or legs.

- Fever.
- Chest pain.
- Weakness.
- Fatigue (tiredness).
- Pain.
- Fall.

Uncommon side effects (may affect up to 1 in 100 people):

- Infection of the breathing passages.
- Bladder infection.
- Eye infection.
- Tonsillitis.
- Fungal infection of the nails.
- Infection of the skin.
- An infection confined to a single area of skin or part of the body.
- Viral infection.
- Skin inflammation caused by mites.
- Decrease in the type of white blood cells that help to protect you against infection.
- White blood cell count decreased.
- Decrease in platelets (blood cells that help you stop bleeding).
- Anaemia.
- Decrease in red blood cells.
- Increase in eosinophils (a type of white blood cell) in your blood.
- Allergic reaction.
- Diabetes or worsening of diabetes.
- High blood sugar.
- Excessive drinking of water.
- Weight loss.
- Loss of appetite resulting in malnutrition and low body weight.
- Increased cholesterol in your blood.
- Elated mood (mania).
- Confusion.
- Decreased sexual drive.
- Nervousness.
- Nightmares.
- Unresponsive to stimuli.
- Loss of consciousness, low level of consciousness.
- Convulsion (fits).
- Fainting.
- Restless urge to move parts of your body.
- Balance disorder.
- Abnormal coordination.
- Dizziness upon standing.
- Disturbance in attention.
- Problems with speech.
- Loss or abnormal sense of taste.
- Reduced sensation of skin to pain and touch.
- Sensation of tingling, pricking, or numbness skin.
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes.
- Sensation of spinning (vertigo).
- Ringing in the ears.
- Ear pain.
- Atrial fibrillation (an abnormal heart rhythm).

- Interruption in conduction between the upper and lower parts of the heart.
- Abnormal electrical conduction of the heart.
- Prolongation of the QT interval from your heart.
- Slow heart rate.
- Abnormal electrical tracing of the heart (electrocardiogram or ECG).
- Fluttering or pounding feeling in your chest (palpitations).
- Low blood pressure.
- Low blood pressure upon standing (consequently, some people taking Risperidone may feel faint, dizzy, or may pass out when they stand up or sit up suddenly).
- Flushing.
- Pneumonia caused by inhaling food.
- Lung congestion.
- Congestion of breathing passages.
- Crackly lung sounds.
- Wheezing.
- Voice disorder.
- Breathing passage disorder.
- Stomach or intestinal infection.
- Stool incontinence.
- Very hard stool.
- Difficulty swallowing.
- Excessive passing of gas or wind.
- Hives (or "nettle rash").
- Itching.
- Hair loss.
- Thickening of skin.
- Eczema.
- Dry skin.
- Skin discoloration.
- Acne.
- Flaky, itchy scalp or skin.
- Skin disorder.
- Skin lesion.
- Increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown.
- Abnormal posture.
- Joint stiffness, joint swelling.
- Muscle weakness.
- Neck pain.
- Frequent passing of urine, inability to pass urine, pain when passing urine.
- Erectile dysfunction, ejaculation disorder.
- Loss of menstrual periods, missed menstrual periods or other problems with your cycle (females).
- Development of breasts in men.
- Leakage of milk from the breasts.
- Sexual dysfunction.
- Breast pain.
- Breast discomfort.
- Vaginal discharge.
- Swelling of the face, mouth, eyes, or lips.
- Chills.
- Increase in body temperature.
- Change in the way you walk.
- Feeling thirsty.

- Feeling unwell.
- Chest discomfort.
- Feeling "out of sorts".
- Discomfort.
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gammaglutamyltransferase) in your blood, increased liver enzymes in your blood.
- Procedural pain.

Rare side effects (may affect up to 1 in 1000 people):

- Infection.
- Inappropriate secretion of a hormone that controls urine volume.
- Sleep walking.
- Sleep-related eating disorder.
- Sugar in the urine.
- Low blood sugar.
- High blood triglycerides (a fat).
- Lack of emotion.
- Inability to reach orgasm.
- Not moving or responding while awake (catatonia).
- Blood vessel problems in the brain.
- Coma due to uncontrolled diabetes.
- Shaking of the head.
- Glaucoma (increased pressure within the eyeball),
- Problems with movement of your eyes.
- Eye rolling.
- Eyelid margin crusting.
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken Risperidone. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine.
- Dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood.
- Dangerously excessive intake of water.
- Irregular heartbeat.
- Trouble breathing during sleep (sleep apnoea).
- Fast, shallow breathing.
- Inflammation of the pancreas.
- Blockage in the bowels.
- Swollen tongue.
- Chapped lips.
- Rash on skin related to drug.
- Dandruff.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).
- Delay in menstrual periods.
- Enlargement of the glands in your breasts.
- Breast enlargement.
- Discharge from the breasts.
- Increased insulin (a hormone that controls blood sugar levels) in the blood.
- Hardening of the skin.
- Decreased body temperature.
- Coldness in arms and legs.
- Symptoms of drug withdrawal.
- Yellowing of the skin and the eyes (jaundice).

Very rare side effects (may affect up to 1 in 10,000 people):

- Life threatening complications of uncontrolled diabetes.
- Serious allergic reaction with swelling that may involve the throat and lead to difficulty breathing.
- Lack of bowel muscle movement that causes blockage.

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone, so these can also be expected with Risperidone:

- Rapid heartbeat upon standing.

Additional side effects in children and adolescents

In general, side effects in children are expected to be similar to those in adults. The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults: feeling sleepy, or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor (shaking), diarrhoea, and incontinence (lack of control) of urine.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risperidone

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Risperidone contains**

The active substance is risperidone

Each Risperidone orodispersible tablet contains either 0.5 mg, 1 mg or 2 mg of risperidone.

The other ingredients are:

polacrillin resin, crospovidone, silica colloidal anhydrous, microcrystalline cellulose (E460), guar gum (E412), mannitol (E421), aspartame (E951), iron oxide red (E172) and magnesium stearate (E572).

What Risperidone looks like and contents of the pack

Risperidone 0.5 mg: Plain or mottled light pink coloured, round, flat tablets engraved with 'M' on one side and 'R05' on the other side.

Risperidone 1 mg: Plain or mottled light pink coloured, round, flat tablets engraved with 'M' on one side and 'R1' on the other side.

Risperidone 2 mg: Plain or mottled light pink coloured, round, flat tablets engraved with 'M' on one side and 'R2' on the other side.

Pack sizes

Risperidone orodispersible tablets are available as:

OPA/Al/PVC- B/L Plain peel paper /PET/Al/HSL perforated blisters packed in cardboard cartons containing 14 x1, 28 x 1, 56 x 1 or 60 x 1 tablets per pack.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mylan
Potters Bar,
Hertfordshire,
EN6 1TL
United Kingdom

Manufacturer:

Gerard Laboratories
35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13
Ireland

Mylan Hungary Kft.,
Mylan utca 1., Komárom, 2900
Hungary.

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