

Package leaflet: Information for the patient

Risperidone Mylan 0.5 mg film-coated tablets

Risperidone Mylan 1 mg film-coated tablets

Risperidone Mylan 2 mg film-coated tablets

Risperidone Mylan 3 mg film-coated tablets

Risperidone Mylan 4 mg film-coated tablets

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

1. What Risperidone Mylan is and what it is used for

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

Risperidone Mylan 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-standing, aggression in intellectually disabled children (at least 5 years of age) and adolescents with conduct disorder.

2. What you need to know before you take Risperidone Mylan

Do not take Risperidone Mylan:

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Risperidone:

- If you are taking furosemide (a ‘water pill,’ 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. Examples include if you have 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 Mylan may cause low blood pressure. Your dose may need to be adjusted.
- If you, or someone else in your family, have a history of an irregular heart rhythm, as this medicine has been associated with potentially serious changes in heart rhythm.
- If 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.
- 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 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.
- 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 the 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 (hypovolemia).
- 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 taking Risperidone Mylan.

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 Mylan 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 cataract (a clouding of the lens of the eye) surgery, this medicine may affect the pupil or the iris (coloured part of the eye) which could 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 in conduct disorder, other causes of aggressive behaviour should have been ruled out.

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

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, dysopiramide, procainamide, propafenone, amiodarone, sotalol), allergies (anti-histamines), some antidepressants (such as paroxetine, fluoxetine, sertraline, fluvoxamine, tricyclic antidepressants (such as amitriptyline) tetracyclic antidepressants (such as maprotiline) or other medicines for mental health conditions (such as paliperidone or phenothiazines 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).
- Medicines that cause low blood potassium or magnesium (e.g. certain diuretics).
- Medicines to treat elevated blood pressure. Risperidone Mylan 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 Mylan 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

- Cimetidine, ranitidine (blockers of the acidity of stomach).
- Itraconazole and ketoconazole (medicines for treating fungal infections).

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 Mylan

Risperidone Mylan with alcohol

You should avoid drinking alcohol when taking Risperidone Mylan.

Pregnancy, breast-feeding and fertility

- The following symptoms may occur in newborn babies, of mothers that have used risperidone in the last trimester (last three months of 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.

Risperidone can rise your levels of a hormone called “prolactin” that 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 Mylan. Do not drive or use any tools or machines without talking to your doctor first.

Risperidone Mylan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

The 2 mg and 6 mg Risperidone Mylan film-coated tablets also contain a colour called sunset yellow (E110) which may cause allergic reactions.

3. How to take Risperidone Mylan

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.

How much to take

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 older 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

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 usual 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 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 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 Mylan should be used with caution in this patient group.

How to take Risperidone Mylan

- You should swallow your tablet with a drink of water.
- Risperidone can be taken with or without food.

The tablets can be divided into equal doses.

If you take more Risperidone Mylan 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 Mylan

- 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 Mylan

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:

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

- Develop lung infections, including serious lung infections such as pneumonia – you may have a very high temperature, cough up phlegm which may be bloody or frothy and feel very unwell.

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

- Experience a sudden change in your mental state, 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, mini-stroke (transient ischaemic attack) or reduced blood flow to the brain.
- Experience an abnormal heart rhythm, such as fluttering of the heart (fibrillation) or very slow or abnormal heart beat (heart block). These may be caused by abnormal electrical conduction of the heart and may be seen as abnormal electrical activity tracing of the heart (ECG). In some cases this can be life threatening.

- Are unresponsive to stimuli (change in the internal or external environment), have a low level of consciousness or fall unconscious, or experience fits (convulsions).
- Experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed.
- Develop diabetes – a condition where the body is unable to control blood sugar levels correctly. You may feel very thirsty yet pass lots of urine, have an increased appetite yet feel tired and lethargic. If left untreated, this can cause you to fall into a coma or, potentially, life threatening complications of uncontrolled diabetes to develop.
- Experience an increase in the number of infections that you get e.g. sore throat, mouth ulcers etc., which may be caused by a decrease in white blood cells including those that help to protect you against bacterial infection.
- Develop a lung infection caused by inhaling of food into the breathing passages or have congestion of the lung (e.g. due to a build-up of phlegm).
- Notice an infection under the skin, normally in the fatty layers of the thigh and buttock (cellulitis).
- Have an inability to urinate or incomplete emptying of the bladder.
- Have severe constipation, which may be due to an obstruction of intestine or a severe hardening and compaction of the faeces.

Rare (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.
- Have severe pain in the stomach which reaches round through the back. This may be a sign of inflammation of the pancreas.
- Develop increased pressure in the eye (glaucoma), which can cause problems with vision and longer term serious problems with eyesight.
- A lower than normal level of sodium in the blood, which may make you feel weak and confused with aching of muscles. This may be due to inappropriate secretion of a hormone (ADH) that causes the body to retain water and dilute the blood, reducing the amount of sodium. This may be associated with a dangerously excessive (more than 2 litres of water per day) intake of water.
- Notice severe weakness or pain in muscles, which may be due to a breakdown of the muscle tissue (rhabdomyolysis).

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

- Experience loss of appetite, unexplained weight loss, nausea, vomiting, stomach pain, difficulty breathing, slow heart beat, unusual muscle pain or feeling weak, tired or uncomfortable. These may be signs of a rare life-threatening complication of uncontrolled diabetes called diabetic ketoacidosis.

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

The following side effects may also happen:

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

- 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.
- Drowsiness, sleepiness.

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

- Fatigue, usual weakness (asthenia), feeling of tiredness, drowsiness, or lack of energy (lethargy), restlessness, inability to sit still, anxiety, depression, agitation, dizziness, feeling exhausted, sleep disorder.
- Vomiting, diarrhoea, constipation, nausea, heartburn or indigestion, abdominal pain or discomfort, sore throat, dry mouth, toothache.
- Weight increased, increase in body temperature (high temperature), increased appetite, decreased appetite.
- Shortness of breath, flu, blurred vision, infection or allergic reactions of the eye which can produce a sticky discharge, sinus infections, nose or sinus congestion, nose bleeding, cough
- Urinary tract infection, bed wetting, inability to control when passing urine (incontinence), unable to pass urine.
- Tremor, muscle spasm, involuntary movements of face or arms and legs, repetitive movements or abnormal postures associated with muscle contractions, joint and muscular pain, back pain.
- fluid retention in the body (e.g. swelling of arms and legs), pain in arms and legs.
- Rash, skin redness, infections of the ear.
- Fast beating heart, chest pain, high blood pressure.
- Falls.
- Blood prolactin hormone level increased.

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

- Excessive drinking of water, thirst, stool incontinence, wind, hoarseness or voice disorder
- High blood sugar.
- Bladder infection, viral and other infections, tonsil infection, stomach infection, yeast infection of nails.
- Drop in blood pressure after standing, low blood pressure, feeling dizzy after changing body position, awareness of heart beating, heart rate decreased.
- Pain when passing urine, frequent passing of urine.
- Confused, disturbance in attention, excessive sleep, nightmares, nervousness, elated mood (mania).
- Liver enzymes increased, 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), increased blood cholesterol.
- Muscle weakness, excessive restlessness associated with muscle spasms and tremor, ear pain, neck pain, joint swelling, abnormal posture, joint stiffness, chest discomfort.
- Skin lesion, skin disorder, dry skin, intense itching of skin, acne, hair loss, eczema (skin inflammation) which may be caused by mites, skin discoloration, thickening of skin, flushing, pins and needle like sensations, 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, breast pain or discomfort, decreased sexual drive, irregular or delayed menstruation, vaginal discharge.
- Fainting, gait disturbance (manner of walking), sluggishness, weight decreased, decreased appetite resulting in malnutrition and low body weight, feeling 'out of sorts', balance disorder, allergy, chills, abnormal coordination, abnormal taste.

- Painful oversensitivity to light, increased blood flow to the eye, dry eye, increase in tears.
- Crackly lung noise, trouble speaking, difficulty swallowing, coarse/whistling sound during breathing.
- Ringing in ears, sensation of spinning and dizziness (vertigo), face oedema.

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

- Inability to reach orgasm, breast enlargement or swollen, hot, tender breasts.
- Dandruff.
- Coldness in arms and legs, tongue swelling, lip inflammation, hardening of parts of the body e.g. skin
- Eyelid margin crusting, eye rolling, problems with eye movement, complications during cataract surgery.
- Lack of emotion.
- Drug withdrawal syndrome.
- Body temperature decreased.
- Fast shallow breathing, trouble breathing during sleep, Sinus arrhythmia (a normal variation in the heart rhythm caused by breathing).
- Tremor of the head.
- Yellowing of the skin and the eyes (jaundice).
- Presence of blood sugar (glucose) in the urine, low blood sugar, raised levels of insulin fats or (triglycerides) in the blood.

Medicines like risperidone have also been reported to cause a drop in blood pressure after standing which is associated with a very large increase in heart rate as the body recovers.

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 HPRA Pharmacovigilance Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risperidone Mylan

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.

1mg: Do not store above 30°C.

For 0.5 mg, 2 mg, 3 mg, 4 mg, 6 mg: This medicine does not require any special storage conditions.

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 Mylan contains

The active substance is risperidone

Each Risperidone Mylan 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:

Risperidone Mylan 0.5 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), propylene glycol (E490), titanium dioxide (E171), talc (E553B), iron oxide red and black (E172)

Risperidone Mylan 1 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), propylene glycol (E490), titanium dioxide (E171), talc (E553B)

Risperidone Mylan 2 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), propylene glycol (E490), titanium dioxide (E171), talc (E553B) and sunset yellow (E110).

Risperidone Mylan 3 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), titanium dioxide (E171), propylene glycol (E490), talc (E553B) and quinolone yellow (E104).

Risperidone Mylan 4 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), titanium dioxide (E171), propylene glycol (E490), talc (E553B) and quinolone yellow (E104) and indigo carmine (E132).

Risperidone Mylan 6 mg film-coated tablets:

Tablet core: Lactose monohydrate, pregelatinised maize starch, cellulose microcrystalline (E460), magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

Film-coating: Hypromellose (E464), titanium dioxide (E171), propylene glycol (E490), talc (E553B) and quinolone yellow (E104) and sunset yellow (E110).

What Risperidone Mylan looks like and contents of the pack

Risperidone Mylan 0.5 mg: Red-brown, round biconvex film-coated tablet marked “0.5” on one side with a breakline on the reverse

Risperidone Mylan 1 mg: White, round, biconvex film-coated tablet marked “1” on one side with a breakline on the reverse

Risperidone Mylan 2 mg: Orange, round, biconvex film-coated tablet, marked “2” on one side with a breakline on the reverse

Risperidone Mylan 3 mg: Yellow, round, biconvex film-coated tablet, marked “3” on one side with a breakline on the reverse

Risperidone Mylan 4 mg: Green, round, biconvex film-coated tablet, marked “4” on one side with a breakline on the reverse

Risperidone Mylan 6 mg: Yellow, round biconvex film-coated tablet, marked “6” on one side with a breakline on the reverse

Pack sizes

Risperidone Mylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg film-coated tablets are packed in blisters containing 20, 28, 30, 50, 56, 60 or 100 film coated tablets.

Risperidone Mylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg are packed in perforated unit dose blisters in pack sizes of (28 x 1), (30 x 1), (56 x 1), (60 x 1) and (100 x 1).

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Limited,
t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate,
Grange Road
Dublin 13

Manufacturer(s)

McDermott Laboratories Limited,
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Mylan Hungary Kft.
H-2900,
Komárom,
Mylan útca 1.
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium tabletten	Risperidon Mylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg filmomhulde
Denmark	Rispemyl 0,5 mg, 1 mg, 2 mg filmovertrukne tabletter
Finland	Rismyl 0.5 mg, 1 mg, 2 mg kalvopäällysteiset tabletit
France	Risperidone Mylan Pharma 1 mg, 2 mg and 4 mg comprimé pelliculé sécable
Germany	Risperidon Mylan 0,5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg filmtabletten
Greece	Risperidone / Generics 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg and 6 mg film-coated Tablets

Ireland	Risperidone Mylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg film-coated tablets
Italy	Risperidone Mylan Pharma
Luxembourg	Risperimylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg and 6 mg comprimés pelliculés
Spain	Risperidona Mylan Pharmaceuticals 0,5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg comprimidos recubiertos con película EFG
Netherlands	Risperidon Mylan 0,5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, filmomhulde tabletten
Norway	Rispemyl 0.5 mg, 1 mg, 2 mg tabletter, filmdrasjerte
Portugal	Risperidona Mylan 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg comprimido revestido por película
Sweden	Rispemyl 0.5 mg, 1 mg, 2 mg filmdragerade tabletter

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