

Package leaflet: Information for the user

Risperger 0.5 mg, 1 mg, 2 mg and 3 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.
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What is in this leaflet:

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

1. What Risperger is and what it is used for

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

Risperger 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. What you need to know before you take Risperger

Do not take Risperger if:

- 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 Risperger.

Warnings and precautions

Talk to your doctor or pharmacist before taking Risperger:

- 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. Risperger 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 pressure, cardiovascular disorder or blood vessel problems in the brain
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

- if you have Parkinson's disease or dementia
- if you are diabetic
- if you have epilepsy
- if you are a man and you have ever had a prolonged or painful erection. If you experience this while taking Risperger, contact your doctor straight away
- if you have problems controlling your body temperature or overheating
- 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.
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If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Risperger.

Risperger 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 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.

Other medicines and Risperger

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 (such as quinidine), allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (e.g. certain diuretics)
- Medicines to treat elevated blood pressure. Risperger 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). Risperger 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 (e.g. 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 Risperger.

Risperger with food, drink and alcohol

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

Pregnancy and breast-feeding

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 taking this medicine.

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The following symptoms may occur in newborn babies, of mothers that have used Risperger 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.

Driving and using machines

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

Risperger contains lactose and sunset yellow

The tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product 0.5/2/3mg only: The tablets also contain sunset yellow FCF (E110), which may cause allergic reactions.

3. How to take Risperger

How much to take

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 Risperger 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 you respond to the treatment.

Children and adolescents

- Children and adolescents under 18 years old should not be treated with Risperger for bipolar mania.

For the treatment of long-standing aggression in people with Alzheimer's dementia**Adults (including elderly people)**

- Your starting dose will usually 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 Risperger 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. Doses increases should be slower in these patients.

Risperidone should be used with caution in this patient group.

How to take Risperger

Always take Risperger exactly as your doctor 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 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 Risperger 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 heart beats or fits.

If you forget to take Risperger

- 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 Risperger

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

Stop taking Risperger and contact your doctor immediately if you experience any of the following:

- an infection with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems. Risperger may cause a severe reduction in the number of white blood cells and your resistance to infection may be decreased. A blood test will be taken to check possible reduction of white blood cells (agranulocytosis, not known). It is important to inform your doctor about your medicine.
- swollen face, tongue or pharynx; difficulty to swallow; hives and difficulties to breath (angioedema, uncommon)
- unexplained muscle pain, muscle cramps or muscle weakness (rhabdomyolysis, rare)
- 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 (Not known)
- fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome"). Immediate medical treatment may be needed (Rare)
- prolonged or painful erection. This is called priapism. Immediate medical treatment may be needed (Not known)
- involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed (Very common)
- a severe allergic reaction resulting in difficulty in breathing and shock (Not known)
- life threatening complications of uncontrolled diabetes (Very rare).
- a coma due to uncontrolled diabetes (Rare)
- sudden swelling of lips and eyes along with difficulty breathing (Not known)
- 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) (Uncommon)

The following side effects may occur:

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.

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

- 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
- 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 increased.

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

- Excessive drinking of water, stool incontinence, thirsty, very hard faeces, hoarseness or voice disorder
- Lung infection caused by inhaling 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 electrical activity tracing of the heart (ECG), abnormal heart rhythm, awareness of heart beating, heart rate increased or decreased
- Urinary incontinence, pain when passing urine, frequent passing of urine
- Confused, disturbance in attention, low level of consciousness, excessive sleep, nervousness, elated mood (mania), lack of energy and interest
- Blood sugar increased, 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 discoloration, 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 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.

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

- Inability to reach orgasm, menstrual disorder
- Dandruff
- Drug 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, body temperature decreased
- 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
- movement disorder
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- Yellowing of the skin and the eyes (jaundice)
- Inflammation of the pancreas.

Not known (frequency cannot be estimated from the available data):

- Dangerously excessive intake of water.
- Low body temperature (hypothermia)
- Complications in new born babies caused by sudden withdrawal of drugs by the mother.

Elderly people

In elderly patients with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

The following side effects have been reported with the use of long acting injection risperidone. Even if you are not being treated with long acting injections of risperidone but you experience any of the following, talk to your doctor.

- Infection of the intestine
- Abscess under the skin, tingling pricking or numbness of skin, inflammation of the skin
- Decrease in white blood cell counts that helps protect you against bacterial infection
- Depression
- Convulsion
- Eye blinking
- Sensation of spinning or swaying
- Slow beating heart, high blood pressure
- Toothache, tongue spasm
- Buttock pain
- Weight decreased.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Risperger

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, foil, carton or bottle 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 to protect the environment.

This medicinal product does not require any special storage conditions.

6. Contents of the pack and other information

What Risperger contains

- The active substance is risperidone. Each Risperger film-coated tablet contains either 0.5, 1, 2 or 3 mg of risperidone.
- The other ingredients are sodium starch glycolate (type A), lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate, sodium laurilsulfate and pregelatinised maize starch.

0.5 mg: Lactose monohydrate, hypromellose (E464), Sunset yellow aluminium lake (E110), Macrogol, Titanium dioxide (E171), Yellow Iron Oxide (E172) and Indigo Carmine aluminium lake (E132).

1 mg: Lactose monohydrate, hypromellose (E464), Macrogol and Titanium dioxide (E171).

2 mg: Lactose monohydrate, hypromellose (E464), Sunset yellow aluminium lake (E110), Macrogol, Titanium dioxide (E171) and Yellow Iron Oxide (E172).

3 mg: Lactose monohydrate, hypromellose (E464), Sunset yellow aluminium lake (E110), Macrogol, Titanium dioxide (E171), Quinoline Yellow Aluminium Lake (E104) and Indigo Carmine aluminium lake (E132)

What Risperger looks like and contents of the pack

Appearance:

0.5 mg tablet: reddish-brown, circular, and biconvex, with break-line

1 mg tablet: white, circular, and biconvex, with break-line

2 mg tablet: peach, circular, and biconvex, with break-line

3 mg tablet: yellow, and round.

The 0.5 mg, 1 mg, and 2 mg may be divided into equal parts.

Packs:

Blister pack (all strengths) of 6, 10, 20, 28, 30, 50, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

McDermott Laboratories Limited t/a Gerard Laboratories,
Baldoye, Dublin 13, Ireland.

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

Finland: Risperidon Mylan 0.25/0.5/1/2/3/4/6 mg tabletti, kalvopäällysteinen

Ireland: Risperger 0.5/1/2/3mg Film-coated Tablets

Sweden: Risperidon Mylan 0.25/0.5/1/2/3/4/6 mg filmdragerad tablett

This leaflet was last revised:

