

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

1. What Rispone is and what it is used for

Rispone contains the active substance risperidone. It belongs to a group of medicines called ‘anti-psychotics’.

Rispone 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.

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

2. What you need to know before you take Rispone

Do not take Rispone

- 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 Rispone.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rispone 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. Rispone 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 know that you have had low levels of white blood cells in the past (which may or may not have been caused by other medicines)
- 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 possible prolactin-dependent tumour
- 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 Rispone.

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking Rispone, your doctor may check your white blood cell counts.

Rispone 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 Rispone, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.

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. If you are planning to have an operation on your eye, make sure you tell your eye doctor that you are taking this medicine.

Older people with dementia

In older people with dementia, there is an increased risk of stroke. You should not take Rispone if you have dementia caused by stroke.

During treatment with Rispone 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. 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 Rispone

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, allergies (anti-histamines), some antidepressants or other medicines for mental problems
- Medicines that cause a slow heart beat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines to treat raised blood pressure. Rispone 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). Rispone taken by itself or with furosemide, may have an increased risk of stroke or death in older 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 (such as medicines 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 Rispone.

Rispone with food, drink and alcohol

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

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 taking this medicine. Your doctor will decide if you can take it.
- The following symptoms may occur in newborn babies, of mothers who have used Rispone 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.
- Risperidone can raise your levels of a hormone called “prolactin” that may impact fertility (see section 4 “Possible side effects”).

Driving and using machines

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

Rispone contains 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.

3. How to take Rispone

Always take this medicine 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 recommended dose is as follows:

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.

Older 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.

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.

Older 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.

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

Adults (including older 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.

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.

Use in children and adolescents

- Children and adolescents under 18 years old should not be treated with Rispone for **schizophrenia or mania**.
- For the treatment of **conduct disorder** 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 Rispone for conduct disorder.

Method of administration

- For oral use.
- You should swallow your tablet with a drink of water.

If you take more Rispone 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.

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If you forget to take Rispono

- 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 Rispono

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 if you experience any of the following serious side effects:

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

- Tardive dyskinesia (twitching or jerking movements that you cannot control in your face, tongue, or other parts of your body). Take action at once if you experience involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of risperidone may be needed.
- 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 or “mini” stroke caused by a sudden loss of blood supply to the brain. You are under special risk, if you have dementia.

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

- Neuroleptic Malignant Syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness). Immediate medical treatment may be needed.
- Priapism (a prolonged penile erection that may require surgical treatment)

Very rare (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

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

- 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.

The following other side effects may happen:

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

- Difficulty falling or staying asleep
- Parkinsonism. This 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.
- Feeling sleepy, or less alert
- Headache.

Common (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
- Risperidone can raise your levels of a hormone called "prolactin" found on a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include in men breast swelling, difficulty in getting or maintaining erections, 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.
- 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, Nosebleeds, Stuffy nose
- Abdominal pain, Abdominal discomfort, Vomiting, Nausea, Constipation, Diarrhea, 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 (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), Anemia, 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
- A 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, A 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), An 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), A 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
- An 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, An increase in body temperature
- A 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 gamma-glutamyltransferase) in your blood, Increased liver enzymes in your blood
- Procedural pain.

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

- Infection
- Inappropriate secretion of a hormone that controls urine volume
- Sugar in the urine, Low blood sugar, High blood triglycerides (a fat)
- Lack of emotion, Inability to reach orgasm
- 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
- Severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure
- Dangerously excessive intake of water
- Irregular heart beat
- Blood clot in the legs, Blood clot in the lungs
- Trouble breathing during sleep (sleep apnea), Fast, shallow breathing
- Inflammation of the pancreas, A blockage in the bowels
- Swollen tongue, Chapped lips, Rash on skin related to drug
- Dandruff
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis)
- A 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 your blood
- Hardening of the skin
- A decrease in body temperature, Coldness in arms and legs
- Symptoms of drug withdrawal
- Yellowing of the skin and the eyes (jaundice).

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

- 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 it can also be expected with Rispono: 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 or pharmacist. 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 Rispono

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 carton, on the blisters/ on the label of the HDPE-bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not use this medicine after 6 months have elapsed from first opening of the HDPE-bottle.

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 Rispono contains

The active substance is risperidone.

Each film-coated tablet contains 6 mg risperidone.

The other ingredients are

Tablet core: cellulose microcrystalline, croscarmellose sodium, lactose monohydrate, magnesium stearate, silica colloidal anhydrous

Tablet coat: yellow iron oxide (E 172), quinoline yellow (E 104), sepiFilm LP 761 (containing: cellulose microcrystalline, hypromellose, stearic acid, titanium dioxide (E 171))

What Rispono looks like and contents of the pack

The film-coated tablets are yellow and oval, with two breaking notches on either side to be divided into thirds.

Rispono is available in blisters containing 10, 20, 28, 30, 40, 50, 60 or 100 film-coated tablets and in HDPE-bottles containing 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer(s)

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Salutas Pharma GmbH, Dieselstr. 5, 70839 Gerlingen, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, SI-1526 Ljubljana, Slovenia.

Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

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

Germany: Risperidon HEXAL 6 mg Filmtabletten

Ireland: Rispono 6 mg Film-Coated Tablets

Luxembourg: Risperidon HEXAL 6 mg Filmtabletten

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