

PACKAGE LEAFLET: Information for the patient

RISOCON

Film-coated tablets – 2 mg

(Risperidone)

Read this leaflet carefully before you start taking this medicine.

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

In this leaflet:

1. What Risocon is and what it is used for
2. Before you take Risocon
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1. WHAT RISOCON IS AND WHAT IT IS USED FOR

Risocon contains risperidone as active substance. Risocon belongs to a group of medicines called ‘anti-psychotics’.

Risocon is used:

- for the treatment of 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;
- for the treatment of mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive; mania occurs in an illness called “manic-depressive disease”;

- in 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.

2. BEFORE YOU TAKE RISOCON

Do not take Risocon if:

- you are allergic (hypersensitive) to risperidone, or any of the excipients of Risocon (listed in Section 6).

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

Take special care with Risocon

Check with your doctor or pharmacist before taking Risocon if:

- you have a heart problem, such as an irregular heart rhythm or if you are prone to low blood pressure or if you are using medicines for your blood pressure; Risocon 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 disorders 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 have been caused by other medicines or other factors);
- 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 abnormal high level of the hormone prolactin in your blood or if you have a tumour, which is possibly dependent on prolactin;
- you or someone else in your family has a history of **venous thrombosis** (blood clots), since 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 taking Risocon.

Your doctor may monitor your white blood cells number because in patients taking risperidone, very rarely, a dangerous decrease of a type of white blood cells needed to fight infection has been noticed.

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

During a surgery of the eye cataract, the pupil (the black circle in the middle of your eye) may not enlarge as needed. Also, the iris (the coloured part of the eye) may become floppy and that may lead to eye damage. If you are planning to have an eye surgery, make sure you tell your eye doctor that you are taking this medicine.

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.

Risperidone given alone or with furosemide, may increase the risk of stroke or death in elderly people with dementia.

Children and adolescents

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

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

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

Taking other medicines with Risocon

Please tell your doctor or pharmacist if you are taking/using, have recently taken/used or you are planning to take/use any other medicines, including medicines obtained without a prescription.

It is especially important to talk to your doctor or pharmacist if you are taking or using 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 (soothing and tiring) 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; Risocon can lower blood pressure;
- medicines for Parkinson's disease (such as levodopa);
- 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 hydrochlorothiazide); Risocon 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 (such as medicines used to treat psychosis or to calm down);
- 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;
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm;
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

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 Risocon.

Taking Risocon with food, drinks and alcohol

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

Pregnancy, breastfeeding and fertility

Talk to your doctor before using Risocon if you are pregnant, trying to become pregnant or breastfeeding.

Your doctor will decide if you can take it.

The following symptoms may occur in newborn babies born from mothers that have taken Risocon in the last trimester (last three months of their pregnancy): shaking, muscle stiffness, and/or weakness, sleepiness, agitation, breathing problems, and difficulty in breast-feeding. If your baby develops any of these symptoms, contact immediately your doctor.

Risocon 2 mg 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 Risocon.

Do not drive or use any tools or machines without talking to your doctor first.

Important information about some of the excipients of Risocon

This medicinal product contains lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Risocon.

3. HOW TO TAKE RISOCON

Always take this medicine exactly as your doctor has told you. Ask your doctor or pharmacist if you are not sure.

The recommended dose is:

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 patients

- 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 - 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 Risocon 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 patients

- 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 - 2 mg twice a day depending on how much you respond to the treatment.

Children and adolescents

Children and adolescents under 18 years old should not be treated with Risocon for mania in a bipolar disorder.

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

Adults (including elderly people)

- Your starting dose will normally be 0.25 mg twice a day.
- Your dose may then be gradually adjusted by your doctor depending on how you respond to the treatment.
- Most people feel better with 0.5 mg twice a day. Some patients may need 1 mg twice a day.

- Treatment duration in patients with Alzheimer's dementia should not be 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 patients group.

How to take Risocon

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 'The recommended dose is'.

Take your tablet with water.

If you take more Risocon than you should

See a doctor immediately. Take the medicine pack with you.

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

If you forget to take Risocon

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and continue as usually. 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 Risocon

You should not stop taking this medicine unless you are 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 Risocon, 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 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 involuntary rhythmic movements of the tongue and face; withdrawal of risperidone may be needed.

Tell your doctor immediately if you experience any of the following rare side effects (may affect up to 1 in 1,000 people):

- 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 in 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;
- experience severe allergic reaction such as: fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash or drop in blood pressure.

The following side effects may occur:

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

- Difficulty falling or staying asleep.
- Parkinsonism: this condition may include: slow or impaired movement, feeling stiff or firm muscles (this makes your movements abnormal), 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 facial expression.

- Feeling sleepy, or less alert.
- Headache.

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

- Pneumonia, bronchitis, common cold symptoms, sinusitis, urinary tract infection, ear infection, feeling like you have the flu.
- Risocon 2 mg may raise the levels of a hormone called "prolactin" found in a blood test (which may or may not cause symptoms). When symptoms of high prolactin occur, they may include breast enlargement in men, 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 the cycle.
- Weight gain, increased appetite, decreased appetite.
- Sleep disorders, irritability, depression, anxiety, restlessness.
- Dystonia: this is a condition involving slow or persistent involuntary contraction of muscles. Any part of the body may be involved (and may result in abnormal posture), but 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.
- Blurred vision, eye infection or conjunctivitis (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, digestion disorders, 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, decreased white blood cell count, 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 level in your blood.
- Euphoria (mania), confusion, decreased sexual drive, nervousness, nightmares.
- 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 Risocon 2 mg may be needed.
- Sudden loss of blood supply to brain (stroke or “mini” stroke).
- Unresponsiveness to stimuli, loss of consciousness, low level of consciousness.
- Convulsions, fainting.
- A restless urge to move parts of your body, balance disorder, abnormal coordination, dizziness upon standing, attention disturbances, problems with speech, loss or abnormal sense of taste, reduced sensation of skin to pain and touch, a sensation of tingling or numbness skin.
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes.
- 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, slow heart rate, abnormal electrical tracing of the heart (stated in electrocardiogram or ECG), palpitations.
- Low blood pressure, low blood pressure upon standing (some people taking Risocon 2 mg may feel faint or dizzy when they stand up or sit up suddenly), flushing.

- Pneumonia caused by accidental inhalation of food in the lungs, lung congestion, congestion of breathing passages, crackly lung noise, wheezing, voice disorder, breathing passage disorder.
- Gasto-intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas.
- Hives, itching, alopecia, thickening of skin, eczema, skin drying, skin discoloration, acne, scalp exfoliation, scalp itching, skin disorder, skin lesions.
- 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 urination, inability to pass urine, pain during urination.
- Erectile dysfunction, ejaculation disorders.
- Loss of menstrual periods, missed menstrual periods or other problems with the cycle (in females).
- Enlargement of breasts in men, leakage of milk, sexual dysfunction, chest pain, breast discomfort, vaginal discharge.
- Swelling of the face, mouth, eyes, or lips.
- Fever, an increase in body temperature.
- A change in the way you walk.
- Feeling thirsty, feeling unwell, chest discomfort, discomfort.
- Increased liver transaminases in your blood, increased GGT (a liver enzyme called gamma-glutamyltransferase) in your blood, increased levels of liver enzymes in the blood.
- Procedural pain.

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

- Infection
- Insufficient secretion of a hormone that controls urine volume.
- Sugar in urine, low blood sugar, high blood triglycerides (a fat).
- Sleep walking, sleep-related eating disorder.
- Lack of emotion, inability to reach orgasm.
- Not moving or responding while awake (catatonia).

- Neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness).
- Blood vessel problems in the brain.
- Coma due to uncontrolled diabetes.
- Shaking of the head.
- Glaucoma (increased intraocular pressure), problems with movement of your eyes, eye rolling, eyelid margin crusting.
- Eye problems during cataract surgery. If you take or have taken Risocon 2 mg during cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken this medicine.
- A dangerously low number of a certain type of white blood cells needed to fight infection.
- Severe allergic reaction characterised by fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes drop in blood pressure.
- A dangerously excessive intake of water.
- Irregular heartbeat.
- Blood clot in the legs, blood clot in the lungs.
- Difficulty in breathing during sleep (sleep apnea), fast, shallow breathing.
- Inflammation of the pancreas, a blockage in the bowel.
- Swollen tongue, chapped lips, rash on skin caused by medication.
- Dandruff.
- Breakdown of muscle fibers and pain in muscles (rhabdomyolysis).
- Menstrual delay, mammary gland enlargement, breast enlargement, discharge from the breasts.
- Increased level of insulin (a hormone that controls blood sugar levels) in the blood.
- Priapism (a prolonged erection that may require surgical treatment).
- Hardening of the skin.
- Low body temperature, decrease of body temperature, coldness in arms and legs.
- Symptoms of drug withdrawal.
- Yellowing of the skin and eyes (jaundice).

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

- Life-threatening complications due to 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 effects have been reported with the use of another medicine called paliperidone that is very similar to risperidone, so these can also be expected with Risocon 2 mg: rapid heartbeat upon standing.

Other 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RISOCON

Keep out of the sight and reach of children!

Do not use after the expiry date which is stated on the blister and carton.

Do not store above 25°C!

6. FURTHER INFORMATION

What Risocon film coated tablets contain

The active substance is risperidone.

One film-coated tablet contains 2 mg risperidone.

The excipients are:

Tablet core: pregelatinised starch, lactose monohydrate, hypromellose, microcrystalline cellulose, colloidal anhydrous silica, sodium laurylsulphate, magnesium stearate, croscarmellose sodium.

Film coating: polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide, black iron oxide.

Pack content

Carton box with 20 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

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