

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

RISPEVON 1: 1 mg film-coated tablet

RISPEVON 2: 2 mg film-coated tablet

RISPEVON 3: 3 mg film-coated tablet

RISPEVON 4: 4 mg film-coated tablet

Risperidone

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking RISPEVON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RISPEVON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What RISPEVON is and what it is used for

RISPEVON 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;
- Behavioural disturbances in people with dementia, who harm themselves or others;
- Conduct and disruptive behaviour disorders in children (aged 5 – 12 years) who are intellectually disabled.

2. What you need to know before you take RISPEVON

Do not take RISPEVON:

- If you are hypersensitive (allergic) to risperidone or any of the other ingredients of RISPEVON (listed in section 6).
- If you If you are pregnant or breastfeeding.
- If you suffer from Parkinson's disease (a disorder that commonly causes stiffness or slowing of movement) and Lewy Body Dementia (a decline in mental ability).

Safety and efficacy in children under the age of 5 years has not been demonstrated.

Warnings and precautions

Special care should be taken with RISPEVON:

- If you If you are planning to have a cataract operation, make sure you tell your eye doctor that you are taking RISPEVON.
- If you suffer from tardive dyskinesia, a neurological disorder characterized by involuntary movements of the face and jaw.

- If you ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- RISPEVON commonly raises levels of a hormone called "prolactin". This may cause side effects such as menstrual disorders or fertility problems in women and breast swelling in men.
- If you are diabetic. As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking RISPEVON, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly.
- 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 suffer from Parkinson's disease. RISPEVON may cause a deterioration of the disease. You and your doctor should discuss this and you should be very aware of any symptoms, indicating its deterioration.
- RISPEVON may cause sudden low blood pressure especially during the initial period, when the appropriate dose for you is being determined.
- If you suffer from epilepsy or fits.
- If you are an elderly person or if you have liver and kidney problems, your doctor may decide to reduce your dosage.
- If you have an abnormally high level of the hormone prolactin in your blood or if you have a possible prolactin-dependent tumour.
- RISPEVON may cause you to gain weight. Significant weight gain may adversely affect your health. Your doctor should regularly measure your body weight. You are advised to refrain from excessive eating in view of the possibility of weight gain.

- If you have problems controlling your body temperature or overheating.
- If you are a man and you have had a history of a prolonged or painful erection.
- Tell your doctor if you have heart problems (e.g. irregular heartbeat). He/she may decide to reduce your dosage.

Other medicines and RISPEVON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Inform your doctor, pharmacist or healthcare professional if you are taking the following:

- Alcohol and medicines that reduce your ability to react, i.e. centrally acting medicines. Do not take alcohol together with RISPEVON.
- Medicines to treat Parkinson's disease (such as levodopa, bromocriptine or pergolide).
- Medicines to treat high blood pressure. RISPEVON may also increase the effects of blood pressure lowering medicines.
- Medicines that increase the activity of the central nervous system (such as methylphenidate).
- Paliperidone, an antipsychotic medicine that changes the effects of chemicals in the brain.
- Medicines that may change the electrical activity of your heart, such as medicines for malaria, heart rhythm problems, allergies (antihistamines), some antidepressants or other medicines for mental problems.
- Clozapine, a sedative medicine used to treat schizophrenia.
- Phenothiazines, medicines used to treat psychosis or to calm down.
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants and venlafaxine.

- Medicines known as beta-blockers that are used to treat high blood pressure.
- Medicines used to treat epilepsy such as carbamazepine, valproate and topiramate.
- Cimetidine and ranitidine, medicines used to treat heartburn.
- Itraconazole and ketoconazole, medicines to treat fungal infections.
- Furosemide, a diuretic (“water pill”), used to reduce extra fluid in the body (oedema) caused by conditions such as heart failure, liver disease and kidney disease.

RISPEVON with food and alcohol

You can take RISPEVON with or without food. No alcohol should be consumed during treatment with RISPEVON.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

RISPEVON may cause impairment of mental alertness. Therefore, you are advised not to drive or operate machinery until you know how you react to RISPEVON.

RISPEVON contains lactose

RISPEVON tablets contain lactose (sugar present in milk). Inform your doctor if you are aware that you have a rare hereditary problem of galactose intolerance, the Lapp lactose deficiency, or glucose-galactose malabsorption. In this case, you should not take RISPEVON.

3. How to take RISPEVON

Do not share medicines prescribed for you with any other person.

Always take RISPEVON exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

For the treatment of schizophrenia

Adults:

Treatment is usually started at a dose of 2mg per day. Your doctor may increase your dose depending on how you respond to the treatment. The total daily dose is usually not more than 6mg.

The total daily dose can be taken as a once daily dose or can be divided into 2 doses a day. Your doctor will tell you which is best for you.

Children:

The use of RISPEVON for treatment of schizophrenia for children under 15 years of age is not recommended.

Behavioural disturbances in patients with dementia:

The usual starting dose is 0,25 mg twice a day. Your doctor may increase your dose, depending on how you respond to the treatment.

Duration of treatment is usually not more than 6 weeks.

Conduct and other disruptive behaviour disorders in children 5 - 12 years of age:

The dose will depend on the child's weight.

Children weighing less than 50 kg:

The usual starting dose of 0,5 mg is given once a day. Your doctor may increase your dose depending on how you respond to the treatment.

Children under 5 years old should not be treated with RISPEVON for conduct disorder.

If you take more RISPEVON than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you forget to take use RISPEVON

Do not take a double dose to make up for forgotten individual doses. 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 stop taking using RISPEVON

Do not stop your treatment because you are feeling better, without consulting with your doctor. When you do so, you should go off your treatment gradually as you may suffer severe symptoms of feeling sick, vomiting, sweating, sleeplessness, muscle stiffness or jerky movements or re-occurrence of your old medical problem.

4. Possible side effects

RISPEVON can have side effects.

Not all side effects reported for RISPEVON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RISPEVON, please consult your health care provider for advice.

If any of the following happens, stop taking RISPEVON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Yellowing of the skin and eyes, also called jaundice.
- These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RISPEVON. You may need urgent medical attention or hospitalisation.

These are all very serious side effects. If you have them, you may have had a serious reaction to RISPEVON. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty to speak or swallow, inability to move eyes, muscle spasm of face, neck and back or twisting movements of the body.
- If you experience a high or low body temperature, dizziness, fast and shallow breathing, fast and weak heartbeat, muscle cramps, paleness, clammy skin, increased thirst or any unusual symptoms.

- If you are a man and experience a prolonged or painful erection.
- A sudden change in your mental state, slurred speech or sudden weakness or numbness of your face, arms or legs, especially on one side of your body.
- Swelling, pain and redness in the legs, which may lead to chest pain and difficulty breathing.
- Convulsion (fits) and fainting

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- In men, breast swelling, difficulty getting or maintaining an erection, decreased sexual desire or general sexual dysfunction may occur.
- In women, breast discomfort, breast leakage, missed menstrual periods and fertility problems may occur.
- Rapid heart rate, high blood pressure and shortness of breath
- Parkinsonism. This is a medical term that includes the following symptoms: increase in saliva secretion or watery mouth, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression on the face, muscle tightness or stiffness, stiff neck, 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
- Drowsiness, fatigue, restlessness, inability to sit still, irritability, anxiety, sleepiness, dizziness, poor attention, feeling exhausted
- Difficulty falling or staying asleep, sleep disorder and feeling agitated and depressed

- Blurry vision, eye infections or “pink eye”
- Sore throat, cough, nose bleeds and stuffy nose
- Lung infections, common cold symptoms, sinus infections, urinary tract infections and feeling like you have the flu
- Stomach pain and discomfort, vomiting, nausea, constipation, runny stomach, indigestion, dry mouth and tooth ache
- Lack to control urination
- Rash and skin redness
- Slow or sustained involuntary contraction of muscles and tremors, back pain, muscle spasms, muscle pains.
- Weight gain, decreased or increased appetite
- Chest pain, swelling, raised body temperature, lack of energy and fatigue
- Frequent falling (imbalanced)

Less frequent

- 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)
- Decrease in the type of white blood cells that help to protect you against infection, white blood cell count decreased, decrease in platelets (blood cells that help you stop bleeding), anaemia, decrease in red blood cells, increase in eosinophils (a type of white blood cell) in your blood
- 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

- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares
- Unresponsive to stimuli, loss of consciousness, low level of consciousness
- Convulsion (fits), fainting
- Chills, an increase in body temperature
- A change in the way you walk
- Not moving or responding while awake (catatonia)
- Shaking of the head
- 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
- Oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- Swelling of the face, mouth, eyes, or lips
- Glaucoma (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting
- Eye problems during cataract surgery
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, Excessive passing of gas or wind
- Swollen tongue, chapped lips, rash on skin related to medicine
- Inflammation of the pancreas, a blockage in the bowels
- Frequent passing of urine, inability to pass urine, pain when passing urine
- 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, dandruff

- Abnormal posture, joint stiffness, joint swelling, muscle weakness, neck pain
- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis)
- An increase of CPK (creatine phosphokinase) in your blood, an enzyme which is sometimes released with muscle breakdown
- Low blood pressure, low blood pressure upon standing (consequently, some people taking RISPEVON may feel faint, dizzy, or may pass out when they stand up or sit up suddenly, flushing)
- Irregular heartbeat
- Erectile dysfunction, ejaculation disorder (males)
- 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
- Inappropriate secretion of a hormone that controls urine volume
- Sugar in the urine, low blood sugar, high blood triglycerides (a fat)
- Increased insulin (a hormone that controls blood sugar levels) in your blood
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your <doctor><or><,><pharmacist><or nurse>. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of RISPEVON.

5. How to store RISPEVON

Store all medicines out of reach of children.

- Store at or below 25 °C
- Store in the original blister
- Keep the blister in the outer carton
- Protect from light / moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RISPEVON contains

- The active substance is risperidone
- The other ingredients are lactose anhydrous, microcrystalline cellulose, colloidal silicon dioxide, sodium starch glycolate, pregelatinized starch, talc, magnesium stearate and hypromellose 2910.

1 mg: Titanium dioxide

2 mg: Titanium dioxide, orange yellow S (E110) aluminium lake

3 mg: Titanium dioxide, ferric oxide yellow.

4 mg: Titanium dioxide, ferric oxide yellow, lake of indigo carmine.

What RISPEVON looks like and contents of the pack

RISPEVON 1: White, capsule shaped, biconvex film coated tablets debossed with 'R1' on one side and '1037'.

RISPEVON 2: Orange, capsule shaped, biconvex film coated tablets debossed with 'R2' on one side and '1038'.

RISPEVON 3: Yellow, capsule shaped, biconvex film coated tablets debossed with 'R3' on one side and '1039'.

RISPEVON 4: Green, capsule shaped, biconvex film coated tablets debossed with 'R4' on one side and '1040'.

The film-coated tablets are packed in Aluminium/ PVC/LDPE/PVdC Blisters in pack sizes of 30 or 60 tablets.

Holder of Certificate of Registration

Trinity Pharma (Pty) Ltd

106 16th Road

Midrand

1686

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Rispevon 1: 43/2.6.5/0039

Rispevon 2: 43/2.6.5/0040

Rispevon 3: 43/2.6.5/0041

Rispevon 4: 43/2.6.5/0042

Access to the corresponding Professional Information

PI will be available with this leaflet in the packaging.