PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

RISPIDE® 0,5, film-coated tablets

RISPIDE® 1, film-coated tablets

RISPIDE® 2, film-coated tablets

RISPIDE® 3, film-coated tablets

RISPIDE® 4, film-coated tablets

RISPIDE® 6, film-coated tablets

Risperidone

RISPIDE 1 contains 1,6 mg sugar (lactose monohydrate) per tablet

RISPIDE 0,5, 2, 3, 4 & 6 are sugar free

Read all of this leaflet carefully before you start taking RISPIDE

- 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.
- RISPIDE 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 RISPIDE is and what it is used for

2. What you need to know before you take RISPIDE

3. How to take RISPIDE

4. Possible side effects

5. How to store RISPIDE

6. Contents of the pack and other information

1. What RISPIDE is and what it is used for

Risperidone belongs to a group of medicines called 'anti-psychotics'. It works by balancing chemical substances in the brain.

RISPIDE may be used to relieve the symptoms of certain mental or behavioural problems.

2. What you need to know before you take RISPIDE

Do not take RISPIDE:

- if you are hypersensitive (allergic) to risperidone or any of the ingredients of RISPIDE (listed in section 6)
- if you are a child younger than 5 years
- if you suffer from Parkinson's disease (a disorder that commonly causes stiffness or slowing of movement) or have been diagnosed with Lewy body dementia (a disease associated with abnormal deposits of a certain type of protein in the brain)
- if you are pregnant or breastfeeding your baby (see "**Pregnancy and breastfeeding**").

Warnings and precautions

Take special care with RISPIDE:

- if you are taking or using furosemide (a "water pill") (see "**Other medicines and RISPIDE**");
- If you are scheduled for a cataract operation (see "**Cataract surgery**" below);

- if you have high blood sugar (diabetes). As diabetes mellitus or worsening of pre-existing diabetes mellitus have been seen with patients taking RISPIDE, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus blood glucose should be monitored regularly. See "**Possible side effects**";
- if you know of any factors which would favour you having a stroke, such as high blood pressure, a previous stroke, cardiovascular disorder or blood vessel problems in the brain;
- if you have Parkinson's disease or dementia;
- if you have ever experienced involuntary movements of the tongue, mouth and face (tardive dyskinesia). Tardive dyskinesia is a possible side effect of RISPIDE (see "**Possible side effects**");
- if you have ever had a condition with symptoms like high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as neuroleptic malignant syndrome (NMS)). NMS is a possible side effect of RISPIDE (see "**Possible side effects**");
- if you have problems controlling your body temperature or overheating;
- if 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);
- 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. RISPIDE may cause low blood pressure. Your dose may need to be adjusted.
- if you have a blood vessel disease;
- if you have epilepsy (seizures/fits), or a history of seizures;
- 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 a man and you have had a history of a prolonged or painful erection (priapism). Priapism is a possible side effect of RISPIDE.

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

Elderly people with dementia

RISPIDE taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia.

RISPIDE may cause a deterioration of Parkinson's disease. You and your doctor should discuss this, and you should be made aware of any symptoms, indicating its deterioration.

Cataract surgery

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 RISPIDE.

Male and female fertility

Risperidone can raise your levels of a hormone called prolactin that may affect male and female fertility.

Weight gain

RISPIDE may cause you to gain weight. Significant weight gain may adversely affect your health. You should monitor your weight and have a moderate food and drink intake to limit weight gain. If you gain weight, discuss it with your doctor.

Benign pituitary adenoma

Tell your doctor if you develop vision problems, headaches, facial numbness or pain and dizziness. Your doctor may want to check if you may have developed a benign tumour on your pituitary gland (a pea-sized body attached to the base of the brain).

Other medicines and RISPIDE

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

You should avoid drinking alcohol when taking RISPIDE (see also "**Taking RISPIDE with food and drink**").

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 (i.e. quinine and mefloquine), heart rhythm problems (e.g. quinidine, dysopiramide, procainamide, propafenone, amiodarone, sotalol), allergies (antihistamines), some antidepressants (i.e. amitriptyline, maprotiline), or medicines affecting body salts (sodium, potassium, magnesium).
- Medicines that cause a slow heartbeat (such as bisoprolol).
- 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 chlorothiazide). RISPIDE taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia. See "**Warnings and precautions**" section above.

The following medicines may reduce the effect of risperidone

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin, valproate (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

- Paliperidone (for mental problems)
- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta-blockers (used to treat for example high blood pressure)
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- 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

- 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 RISPIDE.

Taking RISPIDE with food, drink and alcohol

- You can take RISPIDE with or without food. You should avoid drinking alcohol when taking RISPIDE.

Pregnancy and breastfeeding

You should not take RISPIDE while pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking RISPIDE.

RISPIDE may affect your baby during pregnancy and breastfeeding.

RISPIDE can raise your levels of a hormone called "prolactin" that may impact fertility (see “**Possible side effects**”).

Driving and using machines

RISPIDE may make you feel dizzy, with a lack of focus. You may also have vision problems during treatment with RISPIDE. Do not drive or use any tools or machines without talking to your doctor first.

It is not always possible to predict to what extent RISPIDE may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which RISPIDE affects you.

RISPIDE 1 contains lactose

RISPIDE 1 contains 1,6 mg lactose (sugar present in milk) per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RISPIDE 1.

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take RISPIDE 1**.** Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take RISPIDE

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

Always take RISPIDE exactly as your doctor instructed you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how much to take. This will depend on your medical condition and the disorder you are treated for.

The usual dose is:

For the treatment of schizophrenia

Adults:

Treatment is usually started at a dose of 2 mg 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 6 mg.

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 RISPIDE for treatment of schizophrenia for children under 15 years of age is not recommended.

Elderly:

A starting dose of 0,5 mg twice daily is recommended. Your doctor may increase your dose to 1 to 2 mg twice daily, depending on how you respond to the treatment.

Renal and liver impairment:

If you suffer from renal or liver problems, your doctor will adjust your dosage as necessary.

Behavioural disturbances in adult 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 0,01 mg/kg is given once a day. Your doctor may increase your dose depending on how your child responds to the treatment.
Children under 5 years old should not be treated with RISPIDE for conduct disorder.

Your doctor will also decide for how long your treatment with RISPIDE will last. Do not stop treatment early as your condition may worsen. Always talk to your doctor before you stop taking a medicine.

If you have the impression that the effect of RISPIDE is too strong or too weak, tell your doctor or pharmacist.

You should swallow your tablet with a drink of water.

If you take more RISPIDE 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. 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 RISPIDE

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 miss two or more doses, contact your doctor.

If you stop taking RISPIDE

You should not stop taking RISPIDE unless told to do so by your doctor.

Your symptoms may return. If your doctor decides to stop RISPIDE, your dose may be decreased gradually over a few days, as sudden withdrawal may cause 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

RISPIDE can have side effects.

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

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

- Serious allergic reactions (anaphylaxis/angioedema). You may have rapid swelling of the hands, feet, ankles, lips, skin, tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with very fast heartbeat, heavy sweating and hives.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to RISPIDE. 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:

- If you experience symptoms such as muscle stiffness, a very high temperature, feeling confused, a fast heartbeat and sweating, contact your doctor immediately. These can be signs of a rare but serious condition known as neuroleptic malignant syndrome.
- If you or your caregiver 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.
- Involuntary rhythmic movements of the tongue, mouth, face and extremities (tardive dyskinesia).
- Difficulty to speak or swallow, difficulty to move eyes, muscle spasm of face.

- If you have chest pain, coughing, shortness of breath, difficulty breathing. These may be signs of a blood clot in your lungs (pulmonary embolism).
- Swelling, pain and redness in the legs (venous thrombosis).
- Yellowing of the skin and the eyes (jaundice).
- If you are a man and experience a prolonged or painful erection (priapism).
- Weakness, dizziness, vertigo, double vision or difficulty speaking (cerebral ischaemia).
- Unsteady or jerky movements of the body (movement disorder).
- Pancreatitis (pain, fever, nausea, swollen abdomen).
- Obstruction of intestine (you may have cramps and not be able to have a bowel movement or pass gas, with a swollen abdomen).
- Severe or life-threatening rash with blisters and peeling skin that may start in and around the mouth, nose, eyes, and genitals and spread to other areas of the body (Steven-Johnson syndrome or toxic epidermal necrolysis).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Weight gain, increased or decreased appetite.
- Lactation (leakage of milk) in men or in women who are not breastfeeding (high levels of prolactin hormone in the blood).
- Runny nose, nose bleeds, stuffy nose, coughing, sore throat.
- Lung infections, common cold symptoms, sinus infections, urinary tract infections and feeling like you have the flu.
- Mood changes, feeling aggressive, feeling anxious.
- Problems with concentration and memory.

- Difficulty falling or staying asleep, sleep disorder, feeling agitated, drowsiness.
- Parkinsonism. You may have 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, eye rolling, muscle tightness, stiff neck, muscle stiffness, small, shuffling, hurried steps and lack of normal arm movements when walking, falls.
- Headache
- Fatigue, restlessness, inability to sit still, irritability, anxiety, sleepiness, dizziness, poor attention, feeling exhausted, depression.
- Rapid heart rate, shortness of breath.
- Chest pain, swelling, raised body temperature, lack of energy and fatigue.
- Blurred vision, eye infections or “pink eye”.
- Dry mouth.
- Stomach pain and discomfort, vomiting, nausea, constipation, runny stomach, indigestion, toothache.
- Skin rash, skin redness.
- Slow or sustained involuntary contraction of muscles and tremors, back pain, pain in arms and legs, muscle spasms, muscle pains.
- Frequent falling (imbalanced).
- Urinary incontinence (lack of control over urination), bed wetting.

Less frequent side effects:

- In women: breast discomfort, breast leakage, absent menstrual periods or other problems with your cycle, vaginal discharge, fertility problems.

- In men: swelling of the breasts, sexual dysfunction, erectile dysfunction (difficulty getting or maintaining an erections), ejaculation disorder, decreased sexual drive.
- Decrease in the type of white blood cells that help protect 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. Talk to your doctor if you frequently feel sick.
- Infection of the breathing passages, bladder infection, eye infection, ear 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.
- Stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind.
- 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 of the skin.
- Elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares.
- Unresponsive to stimuli, loss of consciousness, low level of consciousness.
- Feeling lightheaded, fainting
- Chills
- A change in the way you walk
- Not moving or responding while awake (catatonia)
- Shaking of the head or body
- Abnormal posture, joint or back pain, joint stiffness, joint swelling, muscle weakness, chest pain.

- Breakdown of muscle fibres and pain in muscles (rhabdomyolysis).
- An increase of CPK (creatine phosphokinase) in your blood. This is an enzyme which is sometimes released with muscle breakdown.
- Difficulty breathing, infection of the breathing passages, or inflammation of the airways.
- Painful eyes, oversensitive to light, increased blood flow to the eye, eye swelling, dry eye, increase in tears, redness of the eyes, eye movement disorder.
- A floppy iris, which complicates cataract operations.
- Glaucoma (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting.
- Fast beating heart, chest pain, irregular heartbeat.
- 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 (you may feel dizzy when getting up), high blood pressure (you will only know if you have this if your blood pressure is tested), flushing.
- Skin lesion, skin disorder, dry skin, intense itching of skin, acne, dandruff, skin discolouration, thickening of skin, flushing, inflammation of oily skin, eczema.
- Hives (“nettle rash”), hair loss, itchy flaky skin.
- Frequent passing of urine, inability to pass urine, pain when passing urine.
- Anorexia, weight loss.
- Excessive drinking of water, thirst, feeling cold or hot.
- Inappropriate secretion of a hormone that controls urine volume.

- Increased insulin in your blood (insulin is a hormone that controls blood sugar levels), blood sugar in urine increased, worsening diabetes. You may feel thirsty, pass large volumes of urine and feel weak.
- High or low blood sugar, high blood triglycerides or blood cholesterol.
- Increased liver transaminases, increased GGT (a liver enzyme called gamma-glutamyltransferase) or increased liver enzymes in your blood, jaundice.
- Procedural pain
- Persistent slight hyperactivity (hypomania), feeling elated or over-excited, which causes unusual behaviour (mania).

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

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of RISPIDE.

5. How to store RISPIDE

Store all medicines out of reach of children.

Store in the original packaging (in the carton) at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label and carton.

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 RISPIDE contains

The active substance is risperidone.

The other ingredients are:

All tablets contain hypromellose, magnesium stearate, microcrystalline cellulose, and pregelatinised starch.

In addition:

0,5 mg: hypromellose, propylene glycol, quinoline yellow, sunset yellow, talc and titanium dioxide.

1 mg: hypromellose, lactose monohydrate, macrogol and titanium dioxide.

2 mg: hypromellose, propylene glycol, quinoline yellow, talc and titanium dioxide.

3 mg: hypromellose, propylene glycol, sunset yellow, talc and titanium dioxide.

4 mg: hypromellose, indigotine, macrogol, quinoline yellow, talc and titanium dioxide.

6 mg: hypromellose, indigotine, macrogol, propylene glycol, quinoline yellow, talc and titanium dioxide.

What RISPIDE looks like and contents of the pack

RISPIDE 0,5: Cream, round, biconvex tablets with a diameter of approximately 8,1 mm.

RISPIDE 1: White, round, biconvex tablets with a diameter of approximately 8,1 mm.

RISPIDE 2: Yellow, round, biconvex tablets with a diameter of approximately 8,1 mm.

RISPIDE 3: Peach, round, biconvex tablets with a diameter of approximately 8,1 mm.

RISPIDE 4: Green, round, biconvex tablets with a diameter of approximately 8,1 mm.

RISPIDE 6: Light green, round, biconvex tablets with a diameter of approximately 8,1 mm.

Packs of 30 tablets packed in opaque white PVC/PE/PVDC/Aluminium blisters in a cardboard carton.

Not all strengths are necessarily marketed.

Holder of Certificate of Registration

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RISPIDE 4: 44/2.6.5/0677

RISPIDE 6: 44/2.6.5/0678

The manner in which the corresponding Professional Information may be obtained

Please refer to the SAHPRA Repository of Professional Information and Patient Information Leaflets: https://www.sahpra.org.za/pi-pil-repository/.

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