PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 5

RISPERLET® 0,5 mg tablets.

RISPERLET®1 mg tablets.

RISPERLET® 2 mg tablets.

RISPERLET® 3 mg tablets.

Risperidone

RISPERLET tablets contain sugar (Lactose):

Each 0.5 mg film-coated tablet contains 91 mg lactose monohydrate.

Each 1 mg film-coated tablet contains 131 mg lactose monohydrate.

Each 2 mg film-coated tablet contains 130 mg lactose monohydrate.

Each 3 mg film-coated tablet contains 195 mg lactose monohydrate.

Read all of this leaflet carefully before you start using RISPERLET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RISPERLET 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 RISPERLET is and what it is used for.

2. What you need to know before you take RISPERLET.
3. How to take RISPERLET
4. Possible side effects
5. How to store RISPERLET
6. Contents of the pack and other information

1. What RISPERLET is and what it is used for:

RISPERLET contains a substance called Risperidone (a so-called antipsychotic) and is indicated for the treatment of:

Acute and chronic schizophrenic psychoses and related psychosis in which positive symptoms (such as hallucinations, delusions, thought disturbances, hostility, suspiciousness) and/or the negative symptoms (such as blunted affect, emotional and social withdrawal, poverty of speech) are prominent. RISPERLET also alleviates affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. In patients who have shown an initial treatment response, RISPERLET is also effective in maintaining the clinical improvement.

Mania in bipolar disorder. These episodes are characterised by symptoms such as elevated, expansive or irritable mood, inflated self-esteem, decreased need for sleep, pressured speech, racing thoughts, distractibility, or poor judgment, including disruptive or aggressive behaviours.

RISPERLET can also be used to treat disruptive behaviours like aggression, impulsiveness and self-injury in children aged 5-12 years who are intellectually disabled**.**

2. What you need to know before you take RISPERLET

Do not take RISPERLET:

Do not take RISPERLET if you know that you are hypersensitive (allergic) to risperidone or any of the other ingredients of RISPERLET. Allergy can be recognised for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

Do not give RISPERLET to children under 5 years of age with conduct and other disruptive behaviours.

Do not take RISPERLET if you have Parkinson's disease or Lewy Body Dementia.

Warnings and special precautions:

Take special care with RISPERLET 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. RISPERLET can cause low blood pressure. Your dose needs to be adjusted.
- You know of any factors which would increase your chance of you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessels problems in the brain.
- You have 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 lower level of consciousness (also known as Neuroleptic Malignant Syndrome).
- 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). Your doctor may check your white blood cell counts.
- 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 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.

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

RISPERLET can cause you to gain weight. Significant weight gain can adversely affect your health. Your doctor should regularly measure your body weight.

As diabetes mellitus or worsening of pre-existing diabetes mellitus has been seen in patients taking RISPERLET, your doctor should check for signs of high blood sugar. In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly.

RISPERLET commonly raises levels of a hormone called “prolactin”. This may cause side effects such as menstrual disorders or fertility problems in women, breast swelling in men (see POSSIBLE SIDE EFFECTS). If such side effects occur, evaluation of the prolactin level in blood is recommended.

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 RISPERLET.

Elderly people with dementia:

In elderly patients with dementia, there is an increased risk of stroke. You should not take RISPERLET if you have dementia caused by stroke.

During treatment with RISPERLET you should frequently see your doctor.

Medical treatment should be sought straight away if your care-giver notices 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.

Studies in elderly patients with dementia have shown that RISPERLET taken by itself or with furosemide, is associated with a higher rate of death. Tell your doctor if you are taking furosemide. Furosemide is a medicine which is sometimes used to treat high blood pressure, some heart problems or to treat swelling of parts of the body caused by the build up of too much fluid.

Children and adolescents:

- Children and adolescents under 15 years should not be treated with RISPERLET for schizophrenia or mania.
- Before treatment is started for conduct disorder, other causes of aggressive behaviour should have been ruled out.
- If during treatment with RISPERLET tiredness occurs, a change in the time of administration might improve attention difficulties.
- Before treatment is started your, or your child's body weight may be measured and it may be regularly monitored during treatment.
- For the treatment of conduct disorder, the doctor's will prescribe the suitable dose and treatment duration according to the patient's weight. Children under 5 years should not be treated with RISPERLET for conduct disorder.

- A small and inconclusive study has reported an increase in height in children who took RISPERLET, but whether this is an effect of the drug or due to some other reason is not known.

Other medicines and RISPERLET:

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

Some medicines for treating Parkinson's disease (dopamine agonists, e.g. levodopa) may counteract RISPERLET.
If you are taking medicines for high blood pressure, consult your doctor, as taking these medicines together with RISPERLET may cause the blood pressure to drop too low.

RISPERLET should be used with caution when taking medications that may change the electrical activity of the heart, such as but not restricted to: medicines for malaria, heart rhythm disorders, allergies, other antipsychotics, antidepressants, water tablets or other medicines affecting body salts (sodium, potassium, magnesium).
Carbamazepine, a medicine mainly used for epilepsy or trigeminal neuralgia (severe pain attacks in the face), may change the effect of RISPERLET. Therefore, inform your doctor if you start or stop taking carbamazepine.

Fluoxetine and paroxetine, medicines mainly used to treat depression and various anxiety disorders, may increase the level of RISPERLET in your blood. Therefore, tell your doctor if you start and/or stop taking fluoxetine or paroxetine.

Cimetidine and ranitidine, two medicines used to reduce stomach acid, may slightly increase the level of RISPERLET in your blood, but they are unlikely to change the effect of RISPERLET.

Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate).

An antiphychotic medicine called paliperidone may increase the effects of RISPERLET.

Erythromycin, an antibiotic, does not have an effect on level of RISPERLET in the blood.

Rifampicin, an antibiotic used to treat certain infections may reduce the effects RISPERLET.

Itraconazole and ketoconazole (medicines for treating fungal infections) may increase the effects of RISPERLET.

Certain medicines used in the treatment of HIV/AIDS, such as ritonavir may increase the effects of RISPERLET.

Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm may increase the effects of RISPERLET.

Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders may increase the effects of RISPERLET.

Topiramate, a medicine used to treat epilepsy, does not have a significant effect on the level of RISPERLET in the blood.

Galantamine and donezepil, medicines used to treat dementia, do not have an effect on RISPERLET.

RISPERLET does not show an effect on lithium or valproate, two medicines used to treat mania, or on digoxin, a heart medication.

Taking RISPERLET with furosemide, a medicine used to treat conditions such as heart failure and hypertension, may be associated with harmful effects. Tell your doctor if you are taking furosemide (See “Take special care with RISPERLET”).

RISPERLET can enhance the effect of medicines that reduce the ability to react (e.g., "tranquilisers”, narcotic painkillers, certain antihistamines, certain antidepressants). So only take such medicines if your doctor prescribes them.

RISPERLET with food:

You can take RISPERLET with or without food**.**

RISPERLET with alcohol:

RISPERLET can enhance the effects of alcohol, so don’t drink alcohol whilst taking **RISPERLET.**

Pregnancy, Breastfeeding and fertility:

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

If you are pregnant or if you are planning to become pregnant, you should inform your doctor, who will decide if you can take RISPERLET. Shaking, muscle stiffness and/or weakness,

sleepiness, agitation, breathing problems, and difficulty in feeding, have been observed in newborns, if a mother used RISPERLET in the last trimester of her pregnancy.

Do not breastfeed if you are taking RISPERLET. Consult your doctor in that case.

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

Driving and using machines

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

RISPERLET contains lactose:

RISPERLET tablets contain lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking RISPERLET tablets.

RISPERLET 2 mg film-coated tablets also contain sunset yellow (E110) that may cause allergic reactions.

3. How to take RISPERLET:

Do not share medicines prescribed for you with any other person.
Always take RISPERLET exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
RISPERLET comes in the form of oral tablets for swallowing.

You may take RISPERLET either together with or between meals. The oral tablets may be taken with some liquid.

It is very important that the correct amount of RISPERLET be taken, but this will vary from person to person. That is why your doctor will adjust the amount until the desired effect is obtained. Follow your doctor's instructions carefully and do not change or stop the required dosage without consulting him or her first.

Do not share medicines prescribed for you with others.

RISPERLET can be taken in one intake or divided over two intakes per day. The doctor will determine how much is appropriate for the particular situation, and may adjust the dose accordingly, to choose the lowest dose that is best for you.

Please inform your healthcare professional if you have impaired kidney or liver function**,** your doctor will tell you how many tablets is appropriate for your particular situation.

If you take more RISPERLET than you should:

In the event of overdose, one or more of the following signs may occur: reduced consciousness, drowsiness, sleepiness, excessive trembling, excessive muscle stiffness, fast beating heart, and low blood pressure. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medications together with RISPERLET.

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

If you forget to take RISPERLET:

In the initial treatment period:

Take the missed dose as soon as possible instead of your next dose. Then continue to take the remaining doses in the order described above.

Thereafter:

Do not take the missed dose but take your next dose as usual and continue your course.

Important note: never take more than 16 mg per day.

Effects when treatment with RISPERLET is stopped:

You should not stop taking RISPERLET unless told to do so by your doctor. Your symptoms may return. If your doctor decides to stop RISPERLET, your dose may be decreased gradually over a few days.

4. Possible side effects:

RISPERLET can have side effects.

Listed below are adverse reactions related to RISPERLET treatment.

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

Frequent side effects:

- 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.
- Pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu;
- RISPERLET 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, increased or 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 or discomfort, vomiting, nausea, constipation, diarrhoea, 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 discomfort, weakness, fatigue (tiredness), pain;
- Fall.

Less frequent side effects:

- 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), anaemia, 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, 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 RISPERLET may be needed;
- Sudden loss of blood supply to brain (stroke or "mini" stroke);
- 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 of 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 RISPERLET® may feel faint, dizzy, or may pass out when they stand 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 discolouration, acne, dandruff, 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 discomfort, vaginal discharge, breast pain.

- 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, 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.
- 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;
- 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 pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting;
- Irregular heart beat;
- Blood clot in the legs, blood clot in the lungs;
- Trouble breathing during sleep (sleep apnoea), fast, shallow breathing;
- Inflammation of the pancreas, a blockage in the bowels;
- Swollen tongue, chapped lips, rash on skin related to medicine;
- 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;
- Decreased body temperature, coldness in arms and legs;

- Symptoms of drug withdrawal;
- Yellowing of the skin and the eyes (jaundice).
- Life threatening complications of 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
- Eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken RISPERLET. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken RISPERLET.
- 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;
- Increased insulin (a hormone that controls blood sugar levels) in your blood;
- Rapid heartbeat upon standing;
- Priapism (a prolonged penile erection that may require surgical treatment);
- Hardening of the skin;
- Sleep-related eating disorder;
- Sleep walking;
- Not moving or responding while awake (catatonia).

If you notice any side effects nor mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via “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 RISPERLET.

Alternatively, you may report side effects experienced with RISPERLET directly to Janssen Pharmaceutica (see section ‘Holder of the Certificate of Registration’ for contact details or visit www.janssen.com).

5. How to store RISPERLET:

- Store all medicines out of reach of children.
- Keep RISPERLET at or below 25°C (this is at a normal room temperature).
- Store tablets in the original package until required for use.
- The letters "EXP" on the packaging means that the medicine cannot be kept indefinitely. Therefore, you should not use RISPERLET beyond the date printed after "EXP" (month and year), even if it has been stored properly.
- 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 RISPERLET contains:

- The active substance is Risperidone.
- Each film-coated tablet contains 0.5 mg risperidone.
- Each film-coated tablet contains 1 mg risperidone.
- Each film-coated tablet contains 2 mg risperidone.
- Each film-coated tablet contains 3 mg risperidone.

- The other ingredients are lactose, maize starch, cellulose, hypromellose, magnesium stearate, silicon dioxide, sodium laurylsulfate and propylene glycol.

Additionally:

- The 0,5 milligram tablet also contains talc, titanium dioxide and red ferric oxide.
- The 2 milligram tablet also contains talc, titanium dioxide and orange yellow S.
- The 3 milligram tablet also contains talc, titanium dioxide and quinoline yellow.

What RISPERLET looks like and contents of the pack

RISPERLET oral tablets are supplied in cartons containing one or more blisters of 10 tablets each.

RISPERLET 0,5 mg	A brownish red, oblong, biconvex, half-scored film-coated tablet with "Ris 0,5" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERLET 1 mg	A white, oblong, film-coated half-scored tablet with "Ris 1" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERLET 2 mg	A orange, oblong, film-coated half-scored tablet with "Ris 2" inscription on one side and with or without "JANSSEN" inscription on the other side.
RISPERLET 3 mg	A yellow, oblong, film-coated half-scored tablet with "Ris 3" inscription on one side and with or without "JANSSEN" inscription on the other side.

Holder of certificate of registration:

JANSSEN PHARMACEUTICA (Pty.) Ltd.

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1 mg; A40/2.6.5/0728

2 mg; A40/2.6.5/0729

3 mg:42/2.5.6/0385

Access to the corresponding Professional Information:

Included in the carton, accompanying this patient information leaflet.