

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: RISTABBS 0.5, 1 & 2

Dosage Form & Strength: Orally Dispersible Tablets, risperidone 0.5, 1 & 2 mg

CTD, Module 1

PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

RISTABBS 0.5 mg: Each OD tablet contains risperidone.

RISTABBS 1 mg: Each OD tablet contains risperidone.

RISTABBS 2 mg: Each OD tablet contains risperidone.

Contains: Aspartame and Mannitol

RISTABBS 0.5 contains 2 mg aspartame and 32,10 mg mannitol.

RISTABBS 1 contains 2 mg aspartame and 32,10 mg mannitol.

RISTABBS 2 contains 2 mg aspartame and 30,80 mg mannitol.

Read all this leaflet carefully before you start taking RISTABBS

What is in this leaflet

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

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

RISTABBS is a so-called antipsychotic. The active ingredient in **RISTABBS** is risperidone.

RISTABBS is indicated for the treatment of:

Acute and chronic schizophrenic psychoses (mental health problems) and related psychosis in which positive symptoms (such as seeing things that are not there, false beliefs, thought disturbances, hostility, suspiciousness) and/or the negative symptoms (such as difficulty in expressing emotions, emotional and social withdrawal, poor speech) are prominent. **RISTABBS** also relieves affective symptoms (such as depression, guilt feelings, anxiety) associated with schizophrenia. In patients who have shown an initial treatment response, **RISTABBS** 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.

RISTABBS 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 RISTABBS:

Do not take RISTABBS:

- if you are allergic (hypersensitive) to risperidone, or any of the other ingredients of **RISTABBS** listed in section 6. 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 **RISTABBS** to children under 5 years of age with conduct and other disruptive behaviours.
- Do not take **RISTABBS** if you have Parkinson's disease or Lewy Body Dementia.

Warnings and precautions

Take special care with **RISTABBS**:

Tell your doctor or health care provider before taking **RISTABBS** if you have or had:

- 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. **RISTABBS** 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, or blood vessels problems in the brain
- You have experienced uncontrolled movements of the tongue, mouth and face

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- 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 **RISTABBS**.

RISTABBS 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 **RISTABBS**, your doctor should check for signs of high blood sugar.

In patients with pre-existing diabetes mellitus, blood glucose should be monitored regularly.

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RISTABBS 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 section 4). 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 **RISTABBS**.

Elderly people with dementia

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

During treatment with **RISTABBS** 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.

. 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 **RISTABBS** for schizophrenia or mania.

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- Before treatment is started for conduct disorder, other causes of aggressive behaviour should have been ruled out.
- If during treatment with **RISTABBS** 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 **RISTABBS** for conduct disorder.
- A small and inconclusive study has reported an increase in height in children who took **RISTABBS**, but whether this is an effect of the drug or due to some other reason is not known.

Other medicines and RISTABBS:

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Medicines that may influence RISTABBS:

- **RISTABBS** can enhance the effect of alcohol and medicines that reduce the ability to react (e.g., "tranquilisers", narcotic painkillers, certain antihistamines, certain antidepressants). So, do not drink alcohol and only take such medicines if your doctor prescribes them.
- Some medicines for treating Parkinson's disease (dopamine agonists, e.g., levodopa) may counteract **RISTABBS**.

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- If you are taking medicines for high blood pressure, consult your doctor, as taking these medicines together with **RISTABBS** may cause the blood pressure to drop too low.
- **RISTABBS** 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 **RISTABBS**. 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 **RISTABBS** 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 **RISTABBS** in your blood, but they are unlikely to change the effect of **RISTABBS**.
- Erythromycin, an antibiotic, does not have an effect on level of **RISTABBS** in the blood.
- Topiramate, a medicine used to treat epilepsy, does not have a significant effect on the level of **RISTABBS** in the blood.
- Galantamine and donepezil, medicines used to treat dementia, do not have an effect on **RISTABBS**.

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- **RISTABBS** does not show an effect on lithium or valproate, two medicines used to treat mania, or on digoxin, a heart medication.
- Taking **RISTABBS** 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 section 2**).

RISTABBS with food, drink, and alcohol:

You can take **RISTABBS** with or without food. You should avoid drinking alcohol when taking **RISTABBS**.

Pregnancy and breastfeeding and fertility:

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.

Your doctor will decide if you can take **RISTABBS** during pregnancy. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding, have been observed in new-borns, if a mother used **RISTABBS** in the last trimester of her pregnancy.

Breastfeeding

You should not breastfeed your baby whilst taking **RISTABBS**

Driving and using machines:

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Dizziness, tiredness and vision problems may occur during treatment with

RISTABBS. 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 **RISTABBS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **RISTABBS** affects them.

RISTABBS contains aspartame

This medicine contains 2 mg aspartame in each dosage unit which is equivalent to 2 mg/weight. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

RISTABBS contains mannitol

Which may cause you to have a runny tummy.

RISTABBS are essentially “sodium free”.

3. How to take RISTABBS:

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

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

RISTABBS comes in the form of oral tablets for swallowing.

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

It is very important that the correct amount of **RISTABBS** 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.

The usual dose is:

RISTABBS 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 doctor or pharmacist if you have impaired kidney or liver function, your doctor will tell you how many tablets is appropriate for your particular situation.

Your doctor will tell you how long your treatment with **RISTABBS** will last. Do not stop treatment early. If you have the impression that the effect of **RISTABBS** is too strong or too weak, tell your doctor or pharmacist.

If you take more RISTABBS 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 **RISTABBS**.

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

If you forget to take a dose of RISTABBS:

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 a double dose to make up for forgotten individual doses but take your next dose as usual and continue your course.

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

If you stop taking RISTABBS:

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

4. Possible side effects

RISTABBS can have side effects.

Not all side-effects reported for **RISTABBS** are included in this leaflet. Should your general health worsen while taking **RISTABBS**, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

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- 'swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'

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

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

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:

- 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,
- **RISTABBS** 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

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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,

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- 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 **RISTABBS** 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,

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- 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 **RISTABBS** 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,

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- 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 heartbeat,
- 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 drug,

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- 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 **RISTABBS**. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken **RISTABBS**.
- 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.

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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 **RISTABBS**.

5. How to store RISTABBS

RISTABBS should be stored in the original packaging (keep blisters in the carton until required for use).

Store at or below 25 °C.

Protect from moisture and sunlight.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

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

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What RISTABBS contains:

The active substance in **RISTABBS** is risperidone.

Each **RISTABBS** 0.5 mg contains risperidone.

Each **RISTABBS** 1 mg contains risperidone.

Each **RISTABBS** 2 mg contains risperidone.

The other ingredients are acesulfame potassium, acetone, aspartame, basic butylated fumarate, colloidal silicon dioxide, ferric oxide red & yellow, isopropyl alcohol, low-substituted hydroxypropyl cellulose, magnesium aluminometasilicate, mannitol, peppermint flavour, sodium chloride, sodium lauryl sulfate, sodium stearyl fumarate, strawberry flavour, talc.

RISTABBS contains: Aspartame 2 mg.

What RISTABBS looks like and contents of the pack

RISTABBS 0.5 mg: Yellow coloured, mottled, round, flat faced beveled edged tablets, debossed with 'C' on one side and '01' on the other with characteristic flavour.

RISTABBS 1 mg: White, round, flat faced beveled edged tablets, debossed with 'C' on the side and '02' on the other with characteristics flavour.

RISTABBS 2 mg: Blue colored, mottled, round, flat faced beveled edged tablets, debossed with 'C' on one side and '03' on the other with characteristic flavour.

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Forming laminate aluminium-based film and Lidding laminate soft tempered aluminium foil in cold formable blister strips of 10 tablets per strip packed in an outer carton containing 30 tablets.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

New

Registration number

TBI

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **RISTABBS**.