

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

RISABEX[®] 1 mg/ml oral solution

Risperidone

Sugar free

Read all of this leaflet carefully before you start taking this RISABEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- RISABEX 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 RISABEX is and what it is used for
2. What you need to know before you take RISABEX
3. How to take RISABEX
4. Possible side effects
5. How to store RISABEX
6. Contents of the pack and other information

1. What RISABEX is and what it is used for

RISABEX belongs to a group of medicines called 'anti-psychotics'. It 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.
- Mania, where you may feel very excited, elated, agitated, enthusiastic or hyperactive. Mania occurs in an illness called “bipolar disorder”.
- Short-term treatment of conduct disorders (aggression, impulsivity, and self-injury) in intellectually disabled children (at least 5 years of age) and adolescents.

RISABEX can help alleviate the symptoms of your disease and stop your symptoms from coming back.

2. What you need to know before you take RISABEX

Do not take RISABEX if:

- you are allergic (hypersensitive) to risperidone or any of the other ingredients of RISABEX (listed in section 6);
- you have Parkinson's disease or Lewy Body Dementia.

Do not give RISABEX to children under 5 years of age with conduct and other disruptive behaviours, as efficacy and safety in these children have not been proven.

Warnings and precautions

Take special care with RISABEX

Talk to your doctor or pharmacist before taking RISABEX 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. Risperidone as in RISABEX may cause low blood pressure. Your dose may need to be adjusted
- you know of any factors which would favour you having a stroke, such as high blood pressure, cardiovascular disorder or blood vessel problems in the brain
- you have ever experienced involuntary movements of the tongue, mouth and face

- you have ever had a condition whose symptoms include high temperature, muscle stiffness, sweating or a lowered level of consciousness (also known as Neuroleptic Malignant Syndrome)
- you 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)
- you are diabetic
- you have epilepsy
- you are a man and you have ever had a prolonged or painful erection
- you have problems controlling your body temperature or overheating
- you have kidney problems
- you have liver problems
- you have an 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 taking RISABEX.

As dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood has been seen very rarely with patients taking RISABEX, your doctor may check your white blood cell counts.

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

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

RISABEX 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 the 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 RISABEX.

Elderly people with dementia

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

Medical treatment should be sought straight away 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.

During treatment with RISABEX you should frequently see your doctor.

Studies in elderly patients with dementia have shown that RISABEX 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

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

If during treatment with RISABEX 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.

Other medicines and RISABEX

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

RISABEX can enhance the effect of alcohol and medicines that reduce the ability to react (e.g., "tranquilisers", narcotic painkillers, certain antihistamines, certain antidepressants). Do not drink alcohol and only take such medicines if your doctor prescribes them.

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 (such as quinidine and mefloquine), heart rhythm problems (such as amiodarone, quinidine), allergies (antihistamines), some antidepressants (such as amitriptyline, maprotiline) or other medicines for mental problems
- Medicines that cause a slow heartbeat
- Medicines that cause low blood potassium (such as certain diuretics)
- Medicines to treat raised blood pressure. RISABEX can lower blood pressure
- Medicines for Parkinson's disease (such as levodopa)
- Medicines that increase the activity of the central nervous system (psychostimulants, such as methylphenidate)

- Water tablets (diuretics) used for heart problems or swelling of parts of your body due to a build-up of too much fluid (such as furosemide or chlorothiazide). RISABEX taken by itself or with furosemide, may have an increased risk of stroke or death in elderly people with dementia. See “Warnings and precautions”.

The following medicines may reduce the effect of RISABEX:

- Rifampicin (a medicine for treating some infections)
- Carbamazepine, phenytoin, phenobarbital (medicines for epilepsy).

If you start or stop taking such medicines, you may need a different dose of RISABEX.

The following medicines may increase the effect of RISABEX:

- Quinidine (used for certain types of heart disease)
- Antidepressants such as paroxetine, fluoxetine, tricyclic antidepressants
- Medicines known as beta blockers (used to treat high blood pressure)
- Phenothiazines (such as medicines used to treat psychosis or to calm down)
- Cimetidine, ranitidine (blockers of the acidity of stomach)
- Itraconazole and ketoconazole (medicines for treating fungal infections)
- Certain medicines used in the treatment of HIV/AIDS, such as ritonavir
- Verapamil, a medicine used to treat high blood pressure and/or abnormal heart rhythm
- Sertraline and fluvoxamine, medicines used to treat depression and other psychiatric disorders.

If you start or stop taking such medicines, you may need a different dose of RISABEX.

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

RISABEX with food, drink, and alcohol

You can take RISABEX with or without food. RISABEX should be diluted with any non-alcoholic drink, except for tea, and used immediately. You should avoid drinking alcohol when taking RISABEX.

Pregnancy, 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 healthcare provider for advice before taking RISABEX.

Pregnancy

If you are pregnant or if you are planning to become pregnant, you should inform your doctor, who will decide if you can take RISABEX. Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding, have been observed in new-borns, if a mother used RISABEX in the last trimester of her pregnancy.

Breastfeeding

Risperidone as in RISABEX is also excreted in breastmilk. Do not breastfeed if you are taking RISABEX. Consult your doctor in that case.

Driving and using machines

Dizziness, tiredness, and vision problems may occur during treatment with RISABEX. 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 RISABEX 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 RISABEX affects you.

RISABEX contains benzoic acid (E210)

The amount of benzoic acid in each ml of oral solution is 1,5 mg. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in new-born babies (up to 4 weeks old).

RISABEX is not indicated for children under 5 years of age.

3. How to take RISABEX

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

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

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

RISABEX comes in the form of an oral solution which is to be taken by mouth.

You may take RISABEX either together with or between meals. The solution should be mixed with any non-alcoholic drink, except for tea.

It is very important that the correct amount of RISABEX 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.

RISABEX 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.

The usual dose is:**For the treatment of schizophrenia***Adults*

The usual starting dose is 2 mg per day, this may be increased to 4 mg per day on the second day.

Your doctor will decide what dose is the best for you and how long your treatment will last.

Elderly people

Your starting dose will normally be 0,5 mg twice a day and may then be gradually adjusted by your doctor to 1 mg to 2 mg twice a day.

Your doctor will decide what dose is the best for you and how long your treatment will last.

For the treatment of mania*Adults*

The usual starting dose will normally be 2 mg once a day and may be gradually adjusted by your doctor depending on how you respond to the treatment. Your doctor will decide how long your treatment will last.

Elderly people

Your starting dose will normally be 0,5 mg twice a day and may be gradually adjusted by your doctor depending on how you respond to the treatment. Your doctor will decide how long your treatment will last.

For the treatment of conduct disorder in children 5 to 12 years of age

The dose will depend on your child's weight:

For children who weigh less than 50 kg

The starting dose will normally be 0,01 mg/kg once a day and will be adjusted by your doctor depending on how your child responds to the treatment. Your doctor will decide how long the treatment will last.

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

People with kidney or liver problems

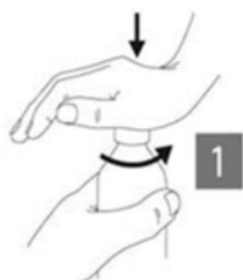
Please inform your healthcare provider if you have impaired kidney or liver function, your doctor will tell you what the appropriate dose is for your particular situation. As a general rule, the starting and follow-up adult doses should be halved.

*Drinkable solution**Measuring your dose*

The solution comes with a pipette (syringe). This should be used to help you measure the exact amount of medicine you need.

Instructions for use

1. The bottle comes with a child resistant cap and should be opened as follows: push the plastic screw cap down while turning it counterclockwise (Figure 1). Remove the unscrewed cap.



2. Insert the pipette into the bottle (Figure 2).



3. While holding the bottom ring, pull the top ring up to the mark that corresponds to the number of millilitres or milligram you need to take / give (Figure 3).



4. Holding the bottom ring, remove the entire pipette from the bottle (Figure 4).



5. Empty the pipette into any non-alcoholic drink, except for tea, by sliding the upper ring down.
6. Close the bottle.
7. Rinse the syringe with some water.

If you take more RISABEX than you should

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

In case of overdose, you may feel sleepy or tired, or have abnormal body movements, problems standing and walking, feel dizzy due to low blood pressure, or have abnormal heartbeats or fits. Cases of abnormal electrical conduction in the heart (QT prolongation) and convulsion have been reported. Overdose can happen if you are taking other medicines together with RISABEX.

If you forget to take RISABEX

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 prescribed order.

Thereafter:

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

Do not take a double dose (two doses at the same time) to make up for forgotten individual doses.

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

If you stop taking RISABEX

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

4. Possible side effects

RISABEX can have side effects.

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

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

- 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 allergic reaction to RISABEX. You may need urgent medical attention or hospitalisation.

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

- experience blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty breathing. If you notice any of these symptoms seek medical advice immediately
- have dementia and experience a sudden change in your mental state or sudden weakness or numbness of your face, arms, or legs, especially on one side, or slurred speech, even for a short period of time. These may be signs of a sudden loss of blood supply to the brain (stroke or “mini” stroke)
- experience fever, muscle stiffness, sweating or a lowered level of consciousness (a disorder called “Neuroleptic Malignant Syndrome”). Immediate medical treatment may be needed
- are a man and experience prolonged or painful erection. This is called “priapism”. Immediate medical treatment may be needed
- experience involuntary rhythmic movements of the tongue, mouth, and face. Withdrawal of RISABEX may be needed

- have yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of jaundice/ 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

- pneumonia, infection of the chest (bronchitis), common cold symptoms, sinus infection, urinary tract infection, ear infection, feeling like you have the flu
- RISABEX 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 or fertility problems
- weight gain, increased appetite, decreased appetite
- 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
- akathisia (this is a feeling of inner restlessness accompanied by mental distress and an inability to sit still)
- 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, abdominal 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 pain, weakness, fatigue (tiredness), pain
- fall.

Less frequent side effects

- infections, e.g. 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

- dangerously low numbers of a certain type of white blood cell needed to fight infection in your blood
- allergic reaction (hypersensitivity)
- inappropriate secretion of a hormone that controls urine volume
- diabetes or worsening of diabetes, high blood sugar, excessive drinking of water
- sugar in the urine, low blood sugar, high blood triglycerides (a fat)
- weight loss, loss of appetite resulting in malnutrition and low body weight
- increased cholesterol in your blood
- dangerously excessive intake of water
- increased insulin (a hormone that controls blood sugar levels) in your blood
- coma due to uncontrolled diabetes
- life threatening complications of uncontrolled diabetes
- elated mood (mania), confusion, decreased sexual drive, nervousness, nightmares
- not moving or responding while awake (catatonia)
- sleep walking
- sleep-related eating disorder
- lack of emotion, inability to reach orgasm
- 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 RISABEX may be needed
- 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 numb skin

- neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)
- shaking of the head
- oversensitivity of the eyes to light, dry eye, increased tears, redness of the eyes
- glaucoma (increased pressure within the eyeball), problems with movement of your eyes, eye rolling, eyelid margin crusting
- eye problems during cataract surgery. During cataract surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken RISABEX. If you need to have cataract surgery, be sure to tell your eye doctor if you take or have taken RISABEX
- 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)
- irregular heartbeat
- low blood pressure, low blood pressure upon standing (consequently, some people taking RISABEX may feel faint, dizzy, or may pass out when they stand up or sit up suddenly), flushing
- blood clot in the legs, blood clot in the lungs
- blood vessel problems in the brain
- pneumonia caused by inhaling food, lung congestion, congestion of breathing passages, crackly lung sounds, wheezing, voice disorder, breathing passage disorder
- trouble breathing during sleep (sleep apnoea), fast, shallow breathing
- stomach or intestinal infection, stool incontinence, very hard stool, difficulty swallowing, excessive passing of gas or wind

- inflammation of the pancreas, a blockage in the bowels
- lack of bowel muscle movement that causes blockage
- swollen tongue, chapped lips, rash on skin related to medicine
- hives (or “nettle rash”), itching, hair loss, thickening of skin, eczema, dry skin, skin discolouration, acne, flaky, itchy scalp or skin, skin disorder, skin lesion
- dandruff
- 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
- breakdown of muscle fibres and pain in muscles (rhabdomyolysis)
- 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 pain, breast discomfort, vaginal discharge
- priapism (a prolonged penile erection that may require surgical treatment)
- a delay in menstrual periods, enlargement of the glands in your breasts, breast enlargement, discharge from the breasts
- chills, an increase in body temperature
- a change in the way you walk
- feeling thirsty, feeling unwell, chest discomfort, feeling “out of sorts”, discomfort
- decreased body temperature, coldness in arms and legs
- symptoms of medicine withdrawal
- 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.

The following side effect has been seen with the use of another medicine called paliperidone that is very similar to risperidone (as in RISABEX), so these can also be expected with RISABEX: rapid heartbeat upon standing.

The following side effects were reported more often in children and adolescents (5 to 17 years) than in adults: feeling sleepy or less alert, fatigue (tiredness), headache, increased appetite, vomiting, common cold symptoms, nasal congestion, abdominal pain, dizziness, cough, fever, tremor (shaking), diarrhoea, and incontinence (lack of control) of urine.

If 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, 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 RISABEX.

5. How to store RISABEX

Store all medicines out of reach of children.

Store at or below 25 °C (this is at normal room temperature). Store in the original package until required for use. Do not freeze.

- Only use for up to 4 months after first opening. After 4 months, take it back to the pharmacy.
- Do not use this medicine after the expiry date (month, year) which is stated on the label after EXP. The expiry date refers to the last day of that month.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Return all unused medicine to your pharmacist. These measures will help to protect the environment.

6. Contents of the pack and other information

What RISABEX contains

- The active substance is risperidone. Each ml of oral solution contains 1 mg of risperidone.
- The other ingredients are tartaric acid (E334), benzoic acid (E211) (as preservative), hydrochloric acid concentrate (for pH adjustment) and purified water.

What RISABEX looks like and contents of the pack

RISABEX is a clear colourless solution.

RISABEX is packed in a Type III amber glass bottle with a plastic (polypropylene/LDPE) child-resistant and tamper-evident cap. RISABEX oral solution is presented in bottle sizes of 30 ml, 60 ml, 100 ml and 120 ml.

Additionally, a dosing pipette (syringe) is supplied in each pack consisting of a polystyrene plunger and a LDPE-barrel and piston.

Not all pack sizes may be marketed.

Holder of the Certificate of Registration

Abex Pharmaceutica (Pty) Ltd

Suite C, Rubenstein Ridge

617 Rubenstein Drive

Moreleta Park, 0181

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Access to the corresponding Professional Information

The professional information will be available on SAHPRA's website
<https://www.sahpra.org.za/pi-pil-repository/>.