

BIO-SULPIRIDE 200 Tablets (Each tablet contains
200 mg sulpiride -30/2.6.5/0511– registered)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S5**

BIO-SULPIRIDE 200, tablets

Sulpiride

Contains sugar (lactose monohydrate 67,0 mg per tablet)

Read all of this leaflet carefully before you start taking BIO-SULPIRIDE 200.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- BIO-SULPIRIDE 200 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 BIO-SULPIRIDE 200 is and what it is used for
2. What you need to know before you take BIO-SULPIRIDE 200
3. How to take BIO-SULPIRIDE 200
4. Possible side effects
5. How to store BIO-SULPIRIDE 200
6. Contents of the pack and other information

1. What BIO-SULPIRIDE 200 is and what it is used for

BIO-SULPIRIDE 200 belongs to a group of medicines called benzamides. It works by blocking the effect of a chemical in the brain.

BIO-SULPIRIDE 200 is used to treat acute episodes of schizophrenia (a mental illness with behaviour problems), and the prevention of future episodes.

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2. What you need to know before you take BIO-SULPIRIDE 200

Do not take BIO-SULPIRIDE 200:

- If you are hypersensitive (allergic) to sulpiride or any of the other ingredients of BIO-SULPIRIDE 200 (listed in section 6).
- If you have a tumour on the adrenal gland called phaeochromocytoma.
- If you are pregnant or breastfeeding your baby.
- If you have bone marrow depression.
- With any other medication that may decrease your white blood cell count or affect the cellular elements of the blood. If you are unsure, please ask your doctor or pharmacist.
- If you have porphyria, which affects your metabolism of medicine.
- If you suffer from prolactin-dependent tumours e.g. pituitary gland prolactinomas and breast cancer. Prolactin is a hormone.
- If you are taking levodopa, amantadine, bromocriptine, cabergoline, lisuride, pergolide, piribedil or ropinirole used for Parkinson's disease (see "Other medicines and BIO-SULPIRIDE 200").
- If you have a heart condition that involves the prolongation of the QT interval.

Warnings and precautions

Take special care with BIO-SULPIRIDE 200 if:

- you have periods of aggressive behaviour or are very agitated
- you have kidney problems
- you have ever had a stroke.
- you have heart problems or a family history of heart problems and your doctor instructed that you should avoid any fall in your blood pressure
- you have Parkinson's disease
- you have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check

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on these.

- you have diabetes
- you are 65 years of age or older
- you have dementia
- you are currently on medication to treat your high blood pressure that belongs to the adrenergic neurone blocker class (e.g. guanethidine). Your dosage may need to be adjusted
- you have epilepsy or have had fits (seizures)
- you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- medicines of this type (antipsychotics) can cause a combination of fever, muscle rigidity and vegetative symptoms, such as sweating or faster breathing (called “neuroleptic malignant syndrome”). If this happens, treatment must be stopped and you should talk to a doctor immediately
- you have high blood pressure
- you have a type of bowel obstruction (ileus)
- you have a digestive problem called congenital digestive stenosis
- you or your family have a history of stomach problems
- you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- you have a history of glaucoma
- you have difficulty passing water (urine)
- you have an enlarged prostate.

During treatment with BIO-SULPIRIDE 200, you should go for regular eye examinations.

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Other medicines and BIO-SULPIRIDE 200

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

You should tell your doctor if you are taking levodopa, amantadine, bromocriptine, cabergoline, lisuride, pergolide, piribedil or ropinirole (used for Parkinson's disease) and do not start taking BIO-SULPIRIDE 200.

Tell your doctor if you are taking any of the following:

- medicines that can affect your electrolyte balance, e.g. stimulant laxatives, tetracosactides, glucocorticoids and IV amphotericin
- medicines to control your heartbeat such as amiodarone, sotalol, quinidine, or disopyramide
- medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil, digitalis or guanfacine
- other medicines for schizophrenia such as pimozide, haloperidol, thioridazine
- lithium, which is used for some types of mental illnesses
- water tablets (diuretics) that can lower the levels of potassium in your blood.
- medicines used for constipation that can lower the levels of potassium in your blood
- medicines used for infections (antibiotics) such as pentamidine, erythromycin or amphotericin B, sparfloracin
- imipramine, a medicine for depression
- methadone
- halofantrine used for malaria
- any antidepressants
- alcohol
- other medicines that can depress the central nervous system such as certain pain medications, cough

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suppressants, medicine to treat anxiety etc.

- medicines for indigestion and heartburn
- sucralfate used for stomach ulcers.

BIO-SULPIRIDE 200 with food and drink

Do not drink alcohol or take medicines that contain alcohol while being treated with BIO-SULPIRIDE 200. This is because alcohol can increase the drowsiness-enhancing effects of BIO-SULPIRIDE 200.

Pregnancy and breastfeeding

You should not take BIO-SULPIRIDE 200 if you are pregnant.

You should not breastfeed your baby if you are taking BIO-SULPIRIDE 200.

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 BIO-SULPIRIDE 200.

Driving and using machines

You may feel sleepy after taking BIO-SULPIRIDE 200; do not drive or operate any machinery if this is the case.

You should not take alcohol or any medicine containing alcohol as it will worsen the sleepy feeling after taking BIO-SULPIRIDE 200.

It is not always possible to predict to what extent BIO-SULPIRIDE 200 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 BIO-SULPIRIDE 200 affects them.

BIO-SULPIRIDE 200 contains lactose.

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

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taking BIO-SULPIRIDE 200.

3. How to take BIO-SULPIRIDE 200

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

Always take BIO-SULPIRIDE 200 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Initial doses are 200 to 800 mg daily in divided doses, 8 or 12 hourly over 24 hours.

Duration is one to six weeks.

Usual maintenance dose is 600 - 800 mg daily in divided doses. Duration is as long as necessary.

BIO-SULPIRIDE 200 should be given in reduced doses to elderly patients and patients with kidney problems.

You doctor will tell you how long your treatment with BIO-SULPIRIDE 200 will last. Do not stop treatment early without consulting your doctor.

If you have the impression that the effect of BIO-SULPIRIDE 200 is too strong or too weak for you, tell your doctor or pharmacist.

If you take more BIO-SULPIRIDE 200 than you should

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

If you forget to take BIO-SULPIRIDE 200

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIO-SULPIRIDE 200 can have side effects.

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Not all side effects reported for BIO-SULPIRIDE 200 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO-SULPIRIDE 200, please consult your healthcare provider for advice.

If any of the following happens, stop taking BIO-SULPIRIDE 200 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, 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 BIO-SULPIRIDE 200. 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:

- you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- you get more infections than usual. This could be because of a blood disorder (agranulocytosis) or a decrease in the number of white blood cells (neutropenia)
- abnormal fast heartbeat, life threatening irregular heartbeat including cardiac arrest, alteration of the heart rhythm (called 'prolongation of QT interval', seen on ECG, electrical activity of the heart)
- yellowing of the skin and eyes, also called jaundice
- movements of the tongue, mouth, jaw, arms and legs that you cannot control
- fits
- neuroleptic malignant syndrome (the syndrome is characterised by fever, involuntary continuous muscle tension and altered mental status such as confusion or memory loss)

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- 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 in breathing. If you notice any of these symptoms seek medical advice immediately. If left untreated, it is possible that it could lead to a blockage of the main artery of the lung (pulmonary embolism). Symptoms of this include very fast or very slow, uneven forceful heartbeats. You may also have problems breathing such as wheezing, shortness of breath, tightness and or pain in your chest.
- muscle breakdown resulting in kidney damage (rhabdomyolysis)
- increased level of creatine phosphokinase in blood (an indicator of muscle damage)

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:

- production of breast milk in men and abnormal production of breast milk in women
- difficulty sleeping (insomnia)
- feeling drowsy or sleepy
- feeling dizzy, light-headed or faint when you stand or sit up quickly
- rigid or stiff muscles, trembling or shaking, difficulty when moving
- feeling restless and not being able to keep still (akathisia)
- weight gain
- painful breasts in men and women, spontaneous flow of milk from the breast
- constipation
- problems with your liver, which will show up on blood tests
- a rash with both flat and raised parts

Less frequent side effects:

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- arms or legs, for example, are stiff and difficult to move
- uncontrolled, involuntary muscle movement
- rolling of the eyes
- lower chambers of the heart (ventricles) beat very quickly or irregular
- feeling dizzy, light-headed or faint when you stand or sit up quickly
- breast enlargement
- loss of menstrual periods and menstrual irregularities
- difficulty in getting or keeping an erection or of ejaculating
- producing more saliva than usual

Side effects with unknown frequency

- blood disorders e.g., low numbers of red blood cells, your body doesn't produce enough new blood cells or low levels of platelets
- feeling confused
- sleep disturbances, overstimulation, feeling agitated, dry mouth, depression
- There have been reports of sudden death with BIO-SULPIRIDE 200. These are possibly caused by heart problems
- high blood pressure
- you develop a lung infection after inhaling food, liquid, saliva or nasal secretions (pneumonia aspiration)
- dilated pupils, small pupils, blurred vision, scarred (white or clouded cornea)
- the level of sugar in your blood is too high
- high cholesterol levels
- blood tests showing less sodium than usual in your blood
- feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH)

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- difficulty urinating and completely emptying the bladder
- problems with your liver, which will show up on blood tests
- sun allergy, is an immune system reaction that is triggered by sunlight
- your neck becomes twisted to one side
- your jaw is tight and stiff
- condition caused when a baby withdraws from certain drugs he's exposed to in the womb before birth
- dangerous drop in body temperature or an abnormally high body temperature or overheating

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 BIO-SULPIRIDE 200.

5. How to store BIO-SULPIRIDE 200

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the securitainer, HDPE container or Patient-Ready-Pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO-SULPIRIDE 200 contains:

BIO-SULPIRIDE 200 Tablets (Each tablet contains 200 mg sulpiride -30/2.6.5/0511– registered)

The active substance is sulpiride 200 mg per tablet.

The other ingredients are lactose, magnesium stearate, povidone, pregelatinised maize starch and sodium starch glycollate.

What BIO-SULPIRIDE 200 looks like and contents of the pack

White circular flat bevelled edged tablet with a breakline on one side and plain on the other side.

50 tablets in either a polypropylene securitainer, HDPE container with screw cap and induction sealing wad or a Patient-Ready-Pack (LDPE bag).

Holder of Certificate of Registration

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