

Package leaflet: Information for the user

Sulpiride Grindeks 50 mg tablets Sulpiride Grindeks 100 mg tablets Sulpiride Grindeks 200 mg tablets

sulpiride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Sulpiride Grindeks is and what it is used for

Sulpiride Grindeks contains a medicine called sulpiride. This belongs to a group of medicines called 'benzamides'. It works by blocking the effect of a chemical in the brain. Sulpiride Grindeks are used to treat schizophrenia.

2. What you need to know before you use Sulpiride Grindeks

Do not use Sulpiride Grindeks

- If you are allergic to sulpiride or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have a tumour of the adrenal gland called 'phaeochromocytoma'.
- If you have a rare illness called 'porphyria' which affects your metabolism.
- If you have breast cancer or cancer in the pituitary gland.
- If you are taking levodopa or ropinirole used for Parkinson's disease (see section *Other medicines and Sulpiride Grindeks* below).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Sulpiride Grindeks.

Check with your doctor or pharmacist before you take this medicine if:

- You have bouts of aggressive behaviour or are very agitated.
- You have kidney problems.
- You have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine.
- You have ever had a stroke.
- You have low levels of potassium in your body (hypokalaemia).
- If 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.
- The person is 65 years of age or older.

- You have dementia.
- You have Parkinson’s disease.
- You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these.
- 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'.
- You have high blood pressure.
- You have a history of glaucoma.
- You have a type of bowel obstruction (ileus).
- You have difficulty passing water (urine).
- You have an enlarged prostate.
- You have a digestive problem called congenital digestive stenosis.
- You or your family have a history of stomach problems.
- You or your family have a history of breast cancer.

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

Children

This medicine should not be used in children younger than 14 years of age.

Other medicines and Sulpiride Grindeks

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription.

Sulpiride Grindeks may affect the way some medicines work. Also some medicines can affect the way Sulpiride Grindeks works.

Do not use and tell your doctor if you are using:

- levodopa or ropinirole used for Parkinson’s disease.

Tell your doctor if you are using any of the following medicines:

- medicines to control your heartbeat such as amiodrone, sotalol, disopyramide or quinidine;
- medicines for high blood pressure or heart disorders such as clonidine, diltiazem, verapamil, or digitalis;
- other medicines for schizophrenia such as pimozide, haloperidol, thioridazine;
- lithium used for some types of mental illness;
- some medicines to help you sleep or lower your anxiety;
- other medicines used to calm emotional and mental problems;
- water tablets (diuretics) that can lower the levels of potassium in your blood;
- some medicines used for constipation (laxatives) that can lower the levels of potassium in your blood;
- some medicines used for infections (antibiotics) such as pentamidine, erythromycin or amphotericin B;
- tetracosactide used to test the function of adrenal gland;
- steroids used to lower inflammation such as prednisolone, betamethasone, dexamethasone;
- some medicines for depression such as imipramine;
- medicines for indigestion and heartburn;
- sucralfate used for stomach ulcers;
- medicines for pain relief. These may also be included in medicines for colds and flu;
- some medicines used for allergies (antihistamines that make you sleepy) such as chlorphenamine, promethazine, ketotifen;
- ropinorole used for Parkinson’s disease;

- methadone used for pain relief and as a drug substitute;
- halofantrine used for malaria.

Sulpiride Grindeks with alcohol

Do not drink alcohol or take medicines that contain alcohol while being treated with Sulpiride Grindeks. This is because alcohol can increase the effects of Sulpiride Grindeks.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Sulpiride Grindeks is not recommended during pregnancy and in women of childbearing potential not using effective contraception.

If you use Sulpiride Grindeks during the last three months of pregnancy, your baby may suffer from agitation, increased muscle tension, involuntary trembling of the body, somnolence, respiratory distress or feeding disorder. Talk to your doctor, if your baby develops any of these symptoms. *Breastfeeding*

You should not breast-feed during therapy with Sulpiride Grindeks. Talk to your doctor about the best way to feed your baby if you are taking Sulpiride Grindeks.

Driving and using machines

You may feel sleepy after taking this medicine. If this happens, do not drive or use any tools or machines.

Sulpiride Grindeks contains lactose

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

3. How to use Sulpiride Grindeks

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.
- The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

How much to take

Adults

The usual starting dose is 400 mg to 800 mg daily depending on your illness. Your doctor may then change your dose depending on your illness.

Patients with kidney disease

The starting dose may be lower and the rate of increasing the dose slower.

Use in children

Sulpiride Grindeks are not recommended for children under 14 years of age.

If you use more Sulpiride Grindeks than you should

If you take more Sulpiride Grindeks than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling restless, confused or agitated, having a reduced level of consciousness, trembling, muscle stiffness or spasm, difficulty in movement, movements that you

cannot control (for example of the eyes, neck, arms and legs), producing more saliva than usual. In some cases dizziness, light-headedness, fainting (due to low blood pressure) and coma have happened. Fatal outcomes have been reported in combination with other medicines which affect the brain.

If you forget to use Sulpiride Grindeks

If you have forgotten to take your regular dose, take it as soon as you remember. If it is almost time to take your next dose, skip the missed dose. Continue to take the medicine as prescribed. Do not take a double dose to make up for a forgotten dose.

If you stop using Sulpiride Grindeks

Keep taking Sulpiride Grindeks until your doctor tells you to stop. Do not stop taking Sulpiride Grindeks just because you feel better. If you stop taking Sulpiride Grindeks suddenly, your illness may come back and you may have other unwanted effects such as feeling or being sick, sweating and difficulty sleeping. In some cases you may also feel restless or have movements that you cannot control (for example of the eyes, neck, arms and legs). Your doctor will gradually lower your dose until you stop your medicine, to prevent these effects happening.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the below you should stop taking Sulpiride Grindeks and visit your doctor or go to a hospital immediately

Uncommon (may affect up to 1 in 100 people)

- You have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs.
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'.

Not known (frequency cannot be estimated from the available data)

- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling.
- You have fits.
- 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.
- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.
- You have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious but rare side effect called 'neuroleptic malignant syndrome'.
- 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).
- 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).
- You have unexplained sore throat or swelling in the neck, armpit and/or groin.
- Muscle breakdown resulting in kidney damage (rhabdomyolysis).
- Increased level of creatine phosphokinase in blood (an indicator of muscle damage).
- Fever.

Tell a pharmacist or doctor as soon as possible if you have any of the following side effects:

Common (may affect up to 1 in 10 people)

- Feeling restless and not being able to keep still (akathisia).

Uncommon (may affect up to 1 in 100 people)

- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure).
- Producing more saliva than usual.

Rare (may affect up to 1 in 1,000 people)

- Rolling of the eyes.

Not known (frequency cannot be estimated from the available data)

- Rigid or still muscles, trembling or shaking, difficulty moving.
- Your neck becomes twisted to one side.
- Your jaw is tight and stiff.
- Increase in blood pressure.
- You feel confused.
- 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).
- Blood tests showing less sodium than usual in your blood.
- Problems with your liver, which will show up on blood tests.
- You develop a lung infection after inhaling food, liquid, saliva or nasal secretions (pneumonia aspiration).

Talk to your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

Common (may affect up to 1 in 10 people)

- Abnormal production of breast milk in men and women.
- Weight gain.
- Painful breasts in men and women.
- Feeling drowsy or sleepy.
- Difficulty sleeping (insomnia).
- Skin rashes.
- Constipation.

Uncommon (may affect up to 1 in 100 people)

- Breast enlargement in men and women.
- Loss of menstrual periods.
- Difficulty in getting or keeping an erection or in ejaculating (impotence), or being unable to have an orgasm.

Not known (frequency cannot be estimated from the available data)

- There have been very rare reports of sudden death with sulpiride. These are possibly caused by heart problems.

Blood tests

Sulpiride Grindeks can increase the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Sulpiride Grindeks

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sulpiride Grindeks contains

– The active substance is sulpiride.
Each tablet contains 50 mg, 100 mg or 200 mg sulpiride.

– The other ingredients are:

Sulpiride Grindeks 50 mg tablets and Sulpiride Grindeks 200 mg tablets

Lactose monohydrate; methylcellulose; potato starch; potato starch, dried; silica, colloidal anhydrous; magnesium stearate; talc.

Sulpiride Grindeks 100 mg tablets

Lactose monohydrate; methylcellulose; potato starch; potato starch, dried; silica, colloidal anhydrous; magnesium stearate; iron oxide red; iron oxide yellow; talc.

What Sulpiride Grindeks looks like and contents of the pack

Sulpiride Grindeks 50 mg are white or almost white round tablets with bevelled edges. Dimension of tablet: diameter approximately 6.0 mm.

Sulpiride Grindeks 100 mg are pink round tablets with bevelled edges. Dimension of tablet: diameter approximately 7.0 mm.

Sulpiride Grindeks 200 mg are white or almost white round tablets with bevelled edges and single score line on one side. Dimension of tablet: diameter approximately 10.0 mm.

Sulpiride Grindeks is available in PVC/Alu blisters of 30 or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

AS GRINDEKS.

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Malta	Sulpiride Grindeks 50 mg tablets Sulpiride Grindeks 100 mg tablets Sulpiride Grindeks 200 mg tablets
Ireland	Sulpiride Grindeks 50 mg tablets Sulpiride Grindeks 100 mg tablets Sulpiride Grindeks 200 mg tablets
United Kingdom	Sulpiride Grindeks 50 mg tablets

(Northern
Ireland)

Sulpiride Grindeks 100 mg tablets

Sulpiride Grindeks 200 mg tablets

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