

Package leaflet: Information for the user

Sulpiride 200mg/5ml Oral Solution

Read all of this leaflet carefully before you start taking 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 your 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 is and what it is used for
2. What you need to know before you take Sulpiride
3. How to take Sulpiride
4. Possible side effects
5. How to store Sulpiride
6. Contents of the pack and other information

1. What Sulpiride is and what it is used for

The name of your medicine is Sulpiride 200mg/5ml Oral Solution (called Sulpiride in this leaflet). It contains sulpiride. This belongs to a group of medicines called benzamides. These act on the brain to reduce abnormal behaviour.

Sulpiride is used for treating schizophrenia.

2. What you need to know before you take Sulpiride

Do not take Sulpiride and tell your doctor if:

- you are allergic to sulpiride or any of the other ingredients of this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have high blood pressure particularly due to a growth on your adrenal glands (phaeochromocytoma)
- you have porphyria, a problem with your metabolism that can cause skin blisters, pain in and around your stomach (abdomen) and brain or nervous system problems
- severe kidney, blood or liver problems
- you have an alcohol-related illness or any other problems that affect your nervous system
- you have ever had breast cancer or a type of brain tumour called 'pituitary prolactinoma'
- you have low numbers of some blood cells in your body due to "bone marrow suppression". You may feel tired, get more infections or bruise more easily than usual
- you are taking levodopa or ropinirole used for Parkinson's disease (see section 'Other medicines and Sulpiride').

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 this medicine.

Warnings and precautions

Talk to your doctor before taking Sulpiride if:

- you have ‘hypomania’. These are mood swings that may show as excitability, anger, irritability and a lower need for sleep
- you have heart problems including unusual heart beats, heart disease or heart failure. If you or members of your family suffer from heart problems, your doctor may give you some tests on your heart and blood before giving you Sulpiride
- 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 high blood pressure
- you have ever had liver problems or a history of jaundice (yellowing of the skin and whites of the eyes)
- you have lung and breathing problems
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have epilepsy
- you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- you have or have had in the past narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- 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 an enlarged prostate gland
- you have had a stroke
- you are an older person as you may be more sensitive to the effects of the medicine
- you have problems with your kidneys
- you have dementia
- you have a type of bowel obstruction (ileus)
- you have difficulty passing water (urine)
- you have a digestive problem called congenital digestive stenosis
- you or someone else in your family has a history of breast cancer.

Sulpiride can make you more sensitive to sunlight. You should avoid being in the sun for long periods and use appropriate protection against the sun.

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

Other medicines and Sulpiride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Sulpiride can affect the way some other medicines work. Also, some medicines can affect the way Sulpiride works.

In particular, do not take this medicine and tell your doctor if you are taking:

- levodopa, used to treat Parkinson’s Disease (sometimes this is called L-dopa).

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

- other medicines to treat Parkinson’s Disease including ropinirole and pramipexole
- medicines to treat high blood pressure or migraine such as beta-blockers, clonidine or diuretics which lower potassium levels (water tablets)
- adrenaline, used for severe allergies and other medicines that mimic the actions of natural substances in the body. These are normally found in cough and cold medicines

- medicines used to treat abnormal heart rhythms (quinidine, disopyramide, amiodarone, sotalol) or angina (diltiazem, verapamil) and other heart problems (digoxin)
- sucralfate, cisapride and antacids used to treat stomach problems or laxatives
- lithium used to treat depression
- medicines used to treat epilepsy
- some medicines used for allergies (antihistamines that make you sleepy) such as chlorphenamine, promethazine, ketotifen
- medicines used to help you sleep or lower your anxiety
- steroids such as prednisolone, dexamethasone and tetracosactide
- medicines to treat infections such as erythromycin or amphotericin B that are injected into a vein or pentamidine that is breathed in or given by injection
- medicines used to treat mental or emotional problems such as pimozide, thioridazine, haloperidol or imipramine
- methadone used for addiction and pain relief
- halofantrine used to treat malaria.

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

Sulpiride with food, drink and alcohol

Do not drink alcohol while taking Sulpiride. This is because Sulpiride can make you drowsy and alcohol will make you even drowsier.

Pregnancy and breast-feeding

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

The following symptoms may occur in newborn babies, of mothers that have used sulpiride in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

You should not take this medicine if you are pregnant or breast feeding unless your doctor thinks it is absolutely necessary.

Driving and using machines

Sulpiride may make you drowsy or less alert to your surroundings. If this happens to you, do not drive or use machinery.

Sulpiride contains methyl (E218) and propyl (E216) parahydroxybenzoate, liquid maltitol (E965), propylene glycol (E1520), glycerine and benzyl alcohol:

- methyl (E218) and propyl (E216) parahydroxybenzoates: May cause allergic reactions (possibly delayed)
- liquid maltitol (E965) (a type of sugar): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 2.3kcal/g.
- propylene glycol (E1520): This medicine contains 109mg propylene glycol in each 5ml dose.
- glycerine: This medicine contains 0.19mg glycerine in each 5ml dose.
- benzyl alcohol: This medicine contains 0.002mg benzyl alcohol in each 5ml dose. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant, breast-feeding, have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Sulpiride

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

Taking this medicine

- this medicine contains 200mg of sulpiride in each 5ml
- take this medicine by mouth.

Adults:

The recommended dose for adults is:

- the doctor will start you on a dose of 200mg (5ml) to 400mg (10ml) two times a day (usually morning and early evening)
- the doctor may reduce the dose or increase it to a maximum of 1200mg (30ml) two times a day
- if you are an older person the dose will be the same as that for adults unless you have a kidney or liver problem. The doctor may lower the dose in this case.

Use in children and adolescents:

This medicine must not be given to children under 14 years of age.

If you take more Sulpiride than you should

If you take more Sulpiride than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken.

If you forget to take Sulpiride

- if you forget a dose, skip the missed dose then go on as before.
- do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Sulpiride

Keep taking this medicine until your doctor tells you to stop, as it may be necessary to lower the dose gradually.

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

4. Possible side effects

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

Stop taking Sulpiride and see a doctor or go to a hospital straight away if:

Common (may affect up to 1 in 10 people)

- you have tremor, stiffness and shuffling (parkinsonism)
- you have trembling, muscle spasms or slow movements (extrapyramidal disorders)

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

- you have very fast or very slow, uneven or forceful heartbeats. You may also have breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain

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

- you have a severe allergic reaction (anaphylactic reaction or anaphylactic shock). The signs may include shock such as difficulty in breathing, dizziness, cold clammy skin, pale skin colour and racing heart beat
- low blood pressure

- alteration of the heart rhythm (called 'Prolongation of QT interval', seen on ECG, electrical activity of the heart)
- you have fits
- 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'
- you have 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
- you have a life threatening irregular heartbeat (Torsade de pointes)
- you have a cardiac arrest
- 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)
- shortness of breath or difficulty breathing
- an infection of the lungs (possibly as a result of inhaling food, liquid or vomit into the lungs)

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, light-headed or faint when you stand or sit up quickly (due to low blood pressure)
- abnormal increase in muscle tension and reduced ability to stretch (hypertonia)
- involuntary and uncontrollable movements (dyskinesia)

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

- rolling of the eyes

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

- your neck becomes twisted to one side
- your jaw is tight and stiff
- decreased body or muscle movement (hypokinesia)
- feeling confused
- high blood pressure
- unusual tiredness, or bruising because of blood disorders
- feeling agitated
- blurred vision, eye changes such as clouding of the lens or colour change
- yellowing of your skin and whites of the eyes (jaundice), inflammation of your liver (hepatitis)
- skin reaction to sunlight
- difficulty in passing water.

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 women
- loss of menstrual periods
- difficulty in getting or keeping an erection or in ejaculating (impotence) or being unable to have an orgasm
- producing more saliva than usual
- you have movements that you cannot control, mainly of the tongue, mouth, jaw, arms and legs (dystonia)

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

- breast enlargement in men
- uncontrollable movements of the mouth, tongue and limbs (tardive dyskinesia)
- tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- feeling depressed
- high blood sugar levels (hyperglycaemia)
- high or low body temperature
- blocked nose
- dry mouth.

There have been reports of unexplained deaths, but it is not proven that they were due to sulpiride.

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.

Blood tests

Sulpiride 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 Yellow Card Scheme www.mhra.gov.uk/Yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sulpiride

- keep this medicine out of the sight and reach of children
- do not store above 25°C
- get rid of the medicine 3 months after opening
- do not use this medicine after the expiry date which is stated on the label and carton (Exp: month, year)
- the expiry date refers to the last day of that month
- do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist

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

6. Contents of the pack and other information

What Sulpiride contains

- the active ingredient is sulpiride.
- the other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), citric acid monohydrate (E330), liquid maltitol (E965), lemon flavour (containing propylene glycol (E1520), glycerine and benzyl alcohol), aniseed flavour (containing propylene glycol (E1520)) and purified water.

What Sulpiride looks like and contents of the pack

A colourless to slightly yellow liquid with an odour of lemon and aniseed.
It comes in a brown glass bottle holding 150ml of liquid.

Marketing Authorisation Holder:

Essential Pharma Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

Manufacturer:

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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