

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sulpiride Tablets 200 mg & 400 mg (sulpiride)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sulpiride is and what it is used for
2. Before you take Sulpiride
3. How to take Sulpiride
4. Possible side effects
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6. Further information

1. WHAT SULPIRIDE IS AND WHAT IT IS USED FOR

Sulpiride belongs to a group of medicines called benzamides. These act on the brain to reduce abnormal behaviour.

Sulpiride is used for treating schizophrenia. Symptoms can include sensing, seeing or hearing things that do not exist, becoming withdrawn and having mistaken beliefs or suspicions.

2. BEFORE YOU TAKE SULPIRIDE

Do not take Sulpiride and tell your doctor if you

- are allergic (hypersensitive) to sulpiride or any of the other ingredients in these tablets. The signs of an allergic reaction include a rash, itching or shortness of breath
- have high blood pressure due to a growth on your adrenal glands (phaeochromocytoma)
- have porphyria, which is a problem with your metabolism which can cause skin blisters, pain in and around your stomach (abdomen) and brain or nervous system problems
- have ever had breast cancer or a type of brain tumour called 'pituitary prolactinoma'
- are taking a medicine called Levodopa (see "Taking other medicines")
- suffer from CNS depression – a condition where the activity of your central nervous system is reduced. Symptoms include feeling sleepy and uncoordinated, staggering, blurred vision, slurred speech, slowed reflexes and breathing,

unconsciousness and coma. Drugs called 'depressants' most often cause this. These include alcohol, barbiturates, opioids, anticonvulsants and anaesthetics.

Take special care with Sulpiride

Before taking this medicine, tell your doctor if you:

- have 'hypomania'. These are mood swings that may show as excitability, anger, irritability, and a lower need for sleep
- have heart problems. If you or members of your family suffer from heart problems, your doctor may carry out some tests on your heart and blood before giving you Sulpiride
- have epilepsy
- have Parkinson's disease
- suffer from kidney problems
- suffer from depression
- suffer from extreme muscular weakness (myasthenia gravis)
- have an enlarged prostate gland (prostatic hypertrophy)
- are susceptible to glaucoma (loss of vision caused by raised pressure in the eye)
- have breathing difficulties
- have yellowing of the skin and/or whites of the eyes (jaundice)
- are elderly and experience dizziness, light-headedness or fainting upon standing (postural hypotension)
- 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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 that Sulpiride works.

In particular, tell your doctor if you are taking any of the following medicines:

- Levodopa, used to treat Parkinson's disease (sometimes this is called L-dopa). You must not take this at the same time as Sulpiride (see 'Do not take Sulpiride' above)
- to treat high blood pressure or migraine such as beta-blockers clonidine or diuretics ('water' tablets)
- 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
- lithium, used to treat depression
- used to treat epilepsy
- steroids such as prednisolone, dexamethasone and tetracosactide
- 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
- ropinirole, used to treat Parkinson's disease
- medicines used to treat mental or emotional problems such as pimozide, thioridazine, haloperidol or imipramine.
- sedatives (sleeping tablets)
- sedating antihistamines
- strong painkillers
- laxatives

Taking Sulpiride with food and drink

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

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

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.

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.

3. HOW TO TAKE Sulpiride

Always take Sulpiride exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Sulpiride Tablets should be swallowed with a glass of water.

Adults (including Elderly)

Your doctor will start you on a dose of 200 mg to 400 mg twice a day (usually morning and early evening). Depending of your response to the treatment, he may reduce the dose or increase it to a maximum of 1200 mg twice a day.

Patient with kidney problems

Your doctor may lower the dose in this case.

Children

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

If you take more Sulpiride than you should

Talk to a doctor or go to a hospital **immediately**. Take the pack of medicine and any remaining tablets with you so the doctor knows what you have taken. Symptoms of overdose include agitation, confusion, uncontrollable movements, low blood pressure, clouding of consciousness and coma.

If you forget to take Sulpiride

If you forget to take a dose, skip the missed dose and 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

Do not suddenly stop taking your medicine as this may cause side effects such as nausea, vomiting, insomnia, sweating and involuntary movement disorders; or the symptoms of your disease may come back. Speak to your doctor first, he may lower your dose gradually.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sulpiride can cause side effects, although not everybody gets them. Elderly patients are more likely to suffer side effects with Sulpiride.

Stop taking this medicine and see a doctor straight away if you have any of the following:

- signs of an allergic reaction: skin rash, flaking skin, boils or sore lips and mouth, sudden wheeziness, fluttering or tightness of the chest or collapse
- unusually fast heartbeats and sweating
- over heating, muscle stiffness, change in consciousness leading to coma.

Other side effects are:

- changes in the rhythm of your heart
- muscle spasms, jerky movements, of your hands or feet, unusual facial movements, shaking or a large amount of saliva in your mouth
- liver problems shown by jaundice (yellowing of your skin and whites of the eyes), feeling sick (nausea), being sick (vomiting), swelling in your upper abdomen,
- feeling more agitated and restless
- having fits (more likely to happen in epileptic patients)
- feeling dizzy when standing up.
- feeling sleepy or drowsy
- unable to sleep
- swelling and breast pain (men or women) and leaking of milk from breasts in women
- irregular or absent menstrual periods
- difficulty achieving orgasm
- impotence
- weight gain.

- 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 clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through the blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE Sulpiride

Keep out of the reach and sight of children.

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

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Sulpiride contains

The active substance is sulpiride. Each tablet contains 200 mg or 400 mg of sulpiride. The other ingredients are maize starch, anhydrous silica, magnesium stearate, microcrystalline cellulose, hydroxypropylcellulose and sodium starch glycollate.

What Sulpiride looks like and contents of the pack

The 200 mg tablet is a white, round tablet with “SD/200” on one side and “G” on the other.

The 400 mg tablet is a white, oblong tablet with “SD/400” on one side and “G” on the other.

Sulpiride Tablets are available in plastic bottles and blister packs containing 10, 12, 15, 20, 24, 28, 30, 50, 56, 60, 84, 96, 100, 112 or 150 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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