

Package leaflet: Information for the user

Sulpiride 200mg Tablets Sulpiride 400mg Film-Coated Tablets Sulpiride (Referred to as Sulpiride Tablets in this leaflet)



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 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 Tablets are and what they are used for
2. What you need to know before you take Sulpiride Tablets
3. How to take Sulpiride Tablets
4. Possible side effects
5. How to store Sulpiride Tablets
6. Contents of the pack and other information

1. What Sulpiride Tablets are and what they are used for

The name of your medicine is Sulpiride Tablets. It contains sulpiride. This belongs to a group of medicines called benzamides. It works by blocking the effect of a chemical in the brain.

Sulpiride is used for treating acute and chronic schizophrenia.

2. What you need to know before you take Sulpiride Tablets

Do not take Sulpiride Tablets:

- If you are allergic to sulpiride or any other ingredients of this medicine (listed in Section 6). The signs of an allergic reaction include a rash, swallowing or breathing problems, swelling of your lips, throat or tongue.
- If you have a tumour on the adrenal gland called 'phaeochromocytoma'
- If you have a rare illness called 'porphyria'
- If you have breast cancer or cancer in the pituitary gland
- If you are taking Levodopa or Ropinirole for Parkinson's disease

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 your doctor or pharmacist before taking Sulpiride Tablets:

- If you have bouts of aggressive behaviour or agitation
- If you have kidney problems
- If you have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine.
- If you have ever had a stroke
- 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
- If you have low levels of potassium in your body (hypokalaemia)
- If the person is 65 years of age or older
- If you have dementia
- If you have Parkinson's disease
- If you have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- If you have epilepsy or have had fits (seizures)
- If you have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- If you have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- If you have high blood pressure
- If you have painful eyes with blurred vision (glaucoma)
- If you have a type of bowel obstruction (ileus)
- If you have difficulty passing water (urine)
- If you have an enlarged prostate
- If you have a digestive problem called congenital digestive stenosis
- If you or someone else in your family has 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 Tablets.

Other medicines and Sulpiride Tablets

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 Tablets can affect the way some other medicines work. Also, some medicines can affect the way Sulpiride Tablets work.

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

- Levodopa or ropinirole used for Parkinson's disease

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

- Medicines to control your heartbeat such as amiodarone, 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 your 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 (anti-histamines that make you sleepy) such as chlorphenamine, promethazine, ketifen
- Methadone used for pain relief and as a drug substitute
- Halofantrine used for malaria

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

Sulpiride Tablets with alcohol

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

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Do not breast-feed if you are taking Sulpiride Tablets. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed talk to your doctor or pharmacist before taking any medicine.

The following symptoms may occur in newborn babies, of mothers that have used Sulpiride Tablets 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

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

Sulpiride Tablets contain lactose

This medicine 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 take Sulpiride Tablets

Always take this medicine exactly as your doctor or pharmacist 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

Adults:

- The recommended dose is 400mg twice daily
- The doctor may reduce the dose to 200mg twice daily or increase it to a maximum of 1200mg twice daily

Patients with Kidney Disease

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

Use in Children:

This medicine is not recommended for children under the age of 14.

If you take more Sulpiride Tablets than you should

If you take more Sulpiride Tablets 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, lightheadedness, fainting (due to low blood pressure) and coma have happened.

If you forget to take Sulpiride Tablets

- If you forget a dose, take another as soon as you remember. If it is almost time for your next dose, do not take the missed dose at all.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Sulpiride Tablets

Keep taking Sulpiride Tablets until your doctor tells you to stop. Do not stop taking Sulpiride Tablets just because you feel better. If you stop taking Sulpiride Tablets 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Sulpiride Tablets 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

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

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

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 (tardiva dyskinesia)

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

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 Tablets 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 pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sulpiride Tablets

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C
- Store in the original package in order to protect from light
- Do not transfer Sulpiride Tablets to another container
- 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 Sulpiride Tablets if you notice a change in the appearance or smell of the medicine. Talk to your pharmacist.
- Do not throw away 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 Tablets contain

- The active ingredient is sulpiride. The tablets come in two strengths of 200mg and 400mg.
- The other ingredients in Sulpiride 200mg Tablets are lactose, microcrystalline cellulose, povidone K30, sodium starch glycolate and magnesium stearate.
- The other ingredients in Sulpiride 400mg Film-Coated Tablets are lactose, microcrystalline cellulose, povidone K30, sodium starch glycolate, magnesium stearate and tablet coating made from titanium dioxide (E171), hydroxypropylmethylcellulose and polyethylene glycol.

What Sulpiride Tablets look like and contents of the pack

Sulpiride 200mg tablets are white, circular tablets marked S200 on one face and CP on the reverse.

Sulpiride 400mg Film-Coated Tablets are white, oval, film-coated tablets marked S400 and breakline on one face and CP on the reverse.

Sulpiride tablets are available in blister strip packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Wockhardt UK Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Limited, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Sulpiride 200mg Tablets	29831/0193
Sulpiride 400mg Film-Coated Tablets	29831/0192

This is a service provided by the Royal National Institute of Blind People.

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