

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sulpiride 200mg Tablets Sulpiride 400mg Film-Coated Tablets Sulpiride

(Refer to as Sulpiride Tablets in this leaflet)



Read all of this leaflet carefully before you start to take this medicine.

- **Keep this leaflet. You may need to read it again while you are receiving your treatment.**
- **If you have any further questions, please 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 Tablets are and what they are used for
2. Before you take Sulpiride Tablets
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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. Before you take Sulpiride Tablets

Do not take Sulpiride Tablets and tell your doctor if:

- you are allergic (hypersensitive) to sulpiride or any other ingredients in these tablets (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- you have high blood pressure 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
- you are taking Levodopa for Parkinson's Disease
- you have a bone-marrow disorder
- you have breast cancer or a tumour in the pituitary gland (prolactinoma)

Sulpiride Tablets should not be given to you if you are semi-conscious or in a coma.

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.

Take special care with Sulpiride Tablets

Before you take Sulpiride Tablets, tell your doctor 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. 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 Tablets
- you have epilepsy
- you have Parkinson's Disease
- you have kidney or liver problems
- you are elderly
- you have dementia
- you have high blood pressure
- you have ever had a stroke
- 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 severe breathing difficulties
- you have Asthma
- you have myasthenia gravis (extreme weakness) or an enlarged prostate
- you have ever suffered from jaundice (yellowing of the skin and eyes)
- you or a member of your family have had glaucoma
- you have bouts of aggressive behaviour or agitation
- you have low levels of potassium in your body.

Sulpiride may make you sensitive to sunlight, so cover up and use sunscreen when out in the sun.

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

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

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

- pramipexole, ropinirole or levodopa (sometimes this is called L-dopa) used to treat Parkinson's Disease. You must not take any of these medicines at the same time as Sulpiride Tablets
- diuretics (water tablets)
- antiarrhythmics, used to steady the heart rhythm, such as amiodarone, sotalol, disopyramide or quinidine
- sucralfate, used for stomach ulcers, and antacids containing aluminium or magnesium hydroxide, used for indigestion. It is recommended you take sulpiride tablets at least two hours before taking sucralfate or these antacids. You should not take sulpiride tablets with or after taking sucralfate or these antacids
- metoclopramide, used to treat nausea and vomiting, or to empty your stomach
- laxatives
- certain drugs used to treat depression, fluoxetine, lithium and tricyclic antidepressants, such as dosulepin
- medicines used to treat epilepsy
- medicines used to treat high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or digitalis
- medicines to treat infections such as amphotericin
- medicines used to treat mental or emotional problems such as pimozide and thioridazine
- medicines used to treat diabetes, such as metformin tablets or an insulin injection
- tranquilisers and sleeping tablets such as diazepam, nitrazepam and temazepam
- strong (opioid) pain killers such as morphine, codeine phosphate and dihydrocodeine
- anaesthetics
- mefloquine and quinine, used to prevent or treat malaria
- terfenadine and misolastine, antihistamines, used to treat hay fever and other allergies
- tetracosactide, used to test the function of your adrenal gland
- glucocorticoids (steroids)
- certain drugs used to treat shock, such as adrenaline, ephedrine and dobutamine
- other antipsychotic medicines such as pimozide and thioridazine, used to treat mental illness.

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

Taking Sulpiride Tablets with food and drink

Do not drink alcohol while taking Sulpiride Tablets. This is because Sulpiride Tablets 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 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

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

Important information about what is in Sulpiride Tablets

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

Take this medicine as your doctor or pharmacist has told you.

Look on the label and ask the doctor or pharmacist if you are not sure.

Taking this medicine

- unless instructed differently, take the tablets with a glass of water.
- take this medicine by mouth.

Adults:

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

Elderly:

- the usual starting dose in the elderly is one quarter to one half of the adult dose.

The dose should be reduced for patients with kidney problems.

Children:

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

If you take more Sulpiride Tablets than you should

If you take more Sulpiride Tablets 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 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 (two doses at the same time) to make up for a forgotten dose.

If you stop taking Sulpiride Tablets

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

Stopping this medication suddenly may lead to withdrawal symptoms such as nausea, vomiting, runny nose, muscle pains insomnia and anxiety.

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 Tablets can cause side effects although not everybody gets them.

Stop taking this medicine and see a doctor straight away if you have an allergic reaction to Sulpiride Tablets.

Signs of an allergic reaction may include:

- any kind of skin rash, flaking skin, boils or sore lips and mouth
- sudden wheezing, fluttering or tightness of the chest or collapse.

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

- A high temperature, sweating, stiff muscles, fast heartbeat, fast breathing and feel confused, drowsy or agitated. These could be the signs of a serious but rare side effect called 'neuroleptic malignant syndrome'
- 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.
- 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 get any of the following side effects, see your doctor as soon as possible:

- muscle spasms, jerky movements of your hands or feet, unusual facial movements
- jaundice, which normally shows as yellowing of your skin and whites of the eyes
- inflammation of your liver (hepatitis). The signs of this include feeling sick (nausea), being sick (vomiting), swelling in your upper abdomen
- feeling more agitated and restless
- having fits
- become delirious or unresponsive with erratic behaviour or movements
- 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 (leucopenia)
- you have a tendency to bleed and/or bruise more easily than usual. This may be due to a low number of platelets in the blood
- feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)

Tell your doctor if you get any of these side effects:

- feeling sleepy or drowsy
- unable to sleep
- nightmares
- swelling and breast pain (men) and secretion of breast milk in women
- enlarged breasts (in men and women)
- irregular or absent periods
- infertility
- weight gain
- increased or decreased sex drive
- constipation
- problems ejaculating and impotence (in men)

- a painful and prolonged erection (in men)
- feeling confused
- blocked nose and blurred vision
- aggression
- skin rashes, pigmentation of the skin or eyes and sensitivity to sunlight
- being unable to stand or sit still
- weakness or spasms of the muscles
- rigid or stiff muscles
- depression
- trembling of the hands and difficulty with walking
- high or low blood pressure
- dry mouth or excessive salivation
- difficulty in swallowing
- difficulty in passing water
- too much glucose in the blood
- too much fat or cholesterol in the blood
- too little salt in the blood
- hypothermia (feeling very cold)
- cataracts.

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.

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 out of the reach and sight 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 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
- 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 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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