

- high or low body temperature
- jaundice, which normally shows as yellowing of your skin and whites of the eyes
- high blood sugar levels (hyperglycaemia), the signs include feeling thirsty, passing urine more than usual and feeling tired
- inflammation of your liver (hepatitis). The signs of this include feeling sick (nausea), being sick (vomiting), swelling in your upper abdomen
- feeling more agitated, restless or confused
- feeling dizzy when standing up. This may be a sign of low blood pressure
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness.

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

- feeling sleepy or drowsy
- unable to sleep
- feeling depressed
- breast swelling and pain (men or women) and secretion of breast milk in women
- irregular or absent periods
- changes in sexual function
- diarrhoea that may be caused by the liquid maltitol in the medicine
- weight gain
- blocked nose
- dry mouth
- constipation
- skin rashes, skin reaction to direct sunlight.

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Sulpor

- 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 Sulpor 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, aniseed flavour and purified water.

What Sulpor 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 and Manufacturer

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

This leaflet was last revised in 11/2011.

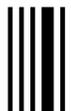
SLS - Safety Warnings



Package leaflet: Information for the user

Sulpor® 200mg/5ml Oral Solution

sulpiride



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.



What is in this leaflet:

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

1. What Sulpor is and what it is used for

The name of your medicine is Sulpor. It contains sulpiride. This belongs to a group of medicines called benzamides. These act on the brain to reduce abnormal behaviour.

Sulpor is used for treating schizophrenia.

2. What you need to know before you take Sulpor

Do not take Sulpor and tell your doctor if:

- you are allergic (hypersensitive) to sulpiride or any other ingredients in this liquid (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 (see section 'Taking other medicines').

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 Sulpor, 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 Sulpor
- 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)

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- you have lung and breathing problems
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have epilepsy
- 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 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.

Sulpor 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 Sulpor.

Other medicines and Sulpor

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 Sulpor can affect the way some other medicines work. Also, some medicines can affect the way Sulpor works.

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

- Levodopa, used to treat Parkinson's Disease (sometimes this is called L-dopa). You must not take this at the same time as Sulpor
- 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 (water tablets)
- medicines used to treat abnormal heart rhythms (quinidine, disopyramide, amiodarone, sotalol) or angina (diltiazem, verapamil) and other heart problems (digoxin)
- 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
- sucralfate, cisapride and antacids used to treat stomach problems or laxatives
- lithium used to treat depression
- medicines used to treat epilepsy
- 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.

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

Sulpor with food, drink and alcohol

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

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

Sulpor 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 this medicine:

Sulpor contains:

- methyl and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine
- liquid maltitol (a type of sugar). If your doctor has told you that you cannot tolerate some sugars, talk to your doctor before taking this medicine.

3. How to take Sulpor

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 usual 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.

Children:

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

If you take more Sulpor than you should

If you take more Sulpor 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 Sulpor

- 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 Sulpor

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 this medicine and see a doctor straight away if you have an allergic reaction to Sulpor.

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:

- 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'
- 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
- changes in the rhythm of your heart beat or heart attack. Symptoms of a heart attack are chest pain which may spread to the shoulders, neck or arms and shortness of breath
- you start having fits.

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, shaking or a large amount of saliva in your mouth
- difficulty in passing water (urine)
- blurred vision, eye changes such as clouding of the lens or colour change in the eye

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