Product:	**Sulpiride 200 mg and 400 mg Tablets**
MA Holder:	**Activase**
PL No.:	**28444/0266-0267**
Pack Size:	**All Packs**
Livery:	**Activase**
Manufacturer:	**-**
Market:	**UK**
Component:	**Leaflet**

Printing Colours:
Black

Non-Printing Colours:
Profile

Dimensions:	**190 x 285 mm**
Created By:	
Artwork Code:	**A0266-0267/O/PIL/A1**
Bar Code:	**-**
Font Type:	**Arial Narrow**
Font Size:	**8.5 pt**

APL

Final Preparation Date For Submission: **26/04/2022**

Packing Site Technical Approval:
00/00/0000

Authority Approval Date: 00/00/0000

Latest Implementation Deadline: 00/00/0000

Print Proof Approval:
00/00/0000

Prompt list for artwork checks

Are the dimensions correct?
Are the font sizes correct?
Are the livery and colours correct?
Is the content (text) correct?
Is the braille correct?
Is the artwork code correct?

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sulpiride 200 mg Tablets
Sulpiride 400 mg Tablets

(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 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

Sulpiride belongs to a group of medicines called 'benzamides'. It works by blocking the effect of a chemical in the brain. Sulpiride tablets are used to treat Schizophrenia.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SULPIRIDE TABLETS

Do not take Sulpiride Tablets:
- If you are allergic (hypersensitive) to sulpiride or any other ingredients in this product (*see Section 6 and end of Section 2*). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have a rare illness called 'porphyria' which affects your metabolism.
- If you have tumour on the adrenal gland called 'phaeochromocytoma'
- If you have breast cancer or cancer in the pituitary gland.
- You are taking levodopa or ropinirole used for Parkinson's disease (see 'Taking other medicines' below)

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 Sulpiride Tablets.

Take special care and tell to your doctor or pharmacist if you:
- have kidney problems
- have high blood pressure
- have epilepsy or have had fits (seizures)
- suffer from mania or hypo-mania, as agitation and aggressive behavior associated with these conditions can be made worse with Sulpiride.
- are elderly (65 years of age or older)
- have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine
- have ever had a stroke
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- have dementia
- have Parkinson's disease
- have low blood levels of Potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- have painful eyes with blurred vision (glaucoma)
- have a type of bowel obstruction (ileus)
- have difficulty passing water (urine)
- have an enlarged prostate
- have a digestive problem called congential digestive stenosis
- 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.

Children:
Not recommended for children under 14 years of age.

Other medicines and Sulpiride
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those medicines obtained without a prescription and herbal medicines. This is because Sulpiride Tablets can affect the way some other medicines work. Also some medicines can affect the way Sulpiride works

Particularly, do not take this medicine and tell your doctor if you are taking
- Medicines used for high blood pressure or heart disorders such as clonidine, diltiazem, verapamil or digitalis.
- Some medicines to help you sleep or lower your anxiety.
- Sucralfate, used for stomach ulcers, and antacids used for indigestion.
- Drugs used for Parkinson's disease, such as levodopa.
- Medicines to control your heartbeat such as amiodarone, sotalol, disopyramide or quinidine
- Other medicines for schizophrenia such as pimozide, haloperidol, thioridazine
- Lithium used for some types of mental illness
- 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
- Medicines for pain relief. These may also be included in medicines for colds and flu
- Some medicines used for allergies such as chlorphenaramine, promethazine, ketotifen
- Ropinarole used for Parkinson's disease
- Methadone used for pain relief and as a drug substitute
- Halofantrine used for malaria

Taking Sulpiride Tablets with food and drink
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 mother's 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.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines
These tablets may cause drowsiness especially at higher dose levels. Do not drive or operate machinery until these symptoms have gone.

Sulpiride tablet contains lactose
Lactose. If you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE SULPIRIDE TABLETS

Always take Sulpiride Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take this medicine by mouth
- Swallow the tablets whole with a glass 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

The recommended dose is
Adults and children over 14:
- The usual starting dose is 400 mg twice daily. This may be reduced to 200 mg twice daily or increased to a maximum of 1200 mg twice daily, depending on how you respond to treatment.
- Your doctor may then change your dose depending on your illness

Children: Not recommended for children under 14 years of age.

Patients with kidney disease: The starting dose may be lower and the rate of increasing the dose slower

If you take more Sulpiride Tablets than you should
If you or someone else swallows several of these tablets all together, contact your doctor or hospital emergency department immediately. Always take any tablets, the leaflet and the box with you as this will allow easier identification of the tablets. 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 miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. 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 tell 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 product, 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 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 (tardive 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 out of the sight and reach of children

Do not store above 25°C. Store in the original package and keep containers tightly closed.

Do not use the tablets after the expiry date is stated on the label.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sulpiride Tablet contains
The **active** ingredient is sulpiride.

The **other** ingredients are lactose monohydrate, microcrystalline cellulose, povidone K30, sodium starch glycollate and magnesium stearate. *(see Section 2 'Important information about some of the other ingredients of Sulpiride Tablets}*.

The tablet coating substances for Sulpiride 400 mg tablets are Titanium dioxide, Hypromellose, Polyethylene Glycol/Macrogol.

What Sulpiride Tablets looks like and contents of the pack
Sulpiride Tablets 200 mg are white, circular tablet marked S200 on one face and plain on the reverse.

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

They are available in blister strip packs of 10, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90,100, 112, 500 and 1000 tablets as well as in container packs of 10, 20, 28, 30, 40, 50, 56, 60, 70, 80, 84, 90,100, 112, 500 and 1000 tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder:
Activase Pharmaceuticals Limited
11 Boumpulinas, 3rd Floor, P.C. 1060, Nicosia, Cyprus

Manufacturer:
Medreich PLC,
Warwick House, Plane Tree Crescent, Feltham, TW13 7HF

This leaflet was last revised in 04/2022.

A0266-0267/O/PIL/A1