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
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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).
• 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

Tell your doctor or pharmacist before taking Sulpiride Tablets:

• If you have:• high blood pressure• painful eyes with blurred vision (glaucoma)• a type of bowel problem called congenital digestive stenosis• a family history of breast cancer• frequent infections such as fever, severe chills, sore throat or mouth infections• a low number of white blood cells (agranulocytosis). This means you may be at risk of developing infection.
• If you have:
  - low levels of potassium in your body (hypokalaemia)
  - kidney problems
  - heart problems or a family history of heart problems. Your doctor may test your heart before taking this medicine.
  - bouts of aggressive behaviour or agitation

Talk your doctor or pharmacist before taking Sulpiride Tablets:

• If you have:
  - a tumour called ‘phaeochromocytoma’
  - a rare illness called ‘porphyria’
  - breast cancer or cancer in the pituitary gland
  - Levodopa or Ropinirole for Parkinson’s disease

3. How to take Sulpiride Tablets

Always take Sulpiride Tablets exactly as your doctor or pharmacist has told you. The recommended dose is 400mg twice daily.

• Adults:
  - Take this medicine by mouth.
  - Swallow the tablets whole with a drink of water.
  - Do not open, break, chew or drain the tablets.
  - Do not share these tablets with other people.
  - Do not discontinue treatment without talking to your doctor or pharmacist, even if you feel better.

Check with your doctor or pharmacist if you are not sure.

Driving and using machines

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

4. Possible side-effects

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

• Medicines to control your heart beat such as amiodarone, sotalol, disopyramide or quinidine
• Medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or diltiazem
• 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 penicillamine, erythromycin or amoxicillin
• Tetraacetic acid 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 isoniazid
• 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 sleep such as chlorphenamine, promethazine, terfenadine.
• Methotrexate used for psoriasis and as a drug substitute
• Haloperidol used for nausea

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

5. How to store Sulpiride Tablets

Keep this medicine in the original package until it is time to take it.

6. Contents of the pack and other information

This medicine is available as:

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

7. Further information

For further information about your medicine, talk to your doctor, nurse or pharmacist.

For the most up-to-date information, visit the following websites:

- www.medicines.org.uk (the NHS medicines website)
- www.nice.org.uk (nice.org.uk)
- www.medicinescomplete.co.uk (www.medicinescomplete.co.uk)
- www.d諴d.gov.uk (www.d諴d.gov.uk)
- www.gov.uk (gov.uk)

8. General information about medicines

Your doctor or pharmacist will have given you information about Sulpiride Tablets that you can read 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.

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

- Medicines to control your heart beat such as amiodarone, sotalol, disopyramide or quinidine
- Medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or diltiazem
- 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
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- Water tablets (diuretics) that can lower the levels of potassium in your blood
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- Medicines for indigestion and heartburn
- Sucralfate used for stomach ulcers
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- Some medicines used for allergies (anti-histamines) that make you sleep such as chlorphenamine, promethazine, terfenadine.
- Methotrexate used for psoriasis and as a drug substitute
- Haloperidol used for nausea

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 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 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.

If you have any further questions, ask your doctor or pharmacist.
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 excited, 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, light-headedness, fainting (due to low blood pressure) and come 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 a life threatening irregular heartbeat (Torsade de pointes)
- 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 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.
- You have chest pain and difficulty breathing.
- You have trembling, muscle spasms or slow movements (extrapyramidal disorders).
- You have severe allergic reaction (anaphylactic reaction or anaphylactic shock).
- You have problems with your eye sight or hearing.
- You have problems with your sense of smell.
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty swallowing.
- You have infection of the mouth, tongue and limbs (tardive dyskinesia).
- You have tremor, stiffness and shuffling (parkinsonism).
- You have very fast or very slow, uneven or forceful heartbeats (cardiac arrhythmia).
- You have severe chest pain and shortness of breath.
- You have very fast or very slow, uneven or forceful heartbeats (cardiac arrhythmia).
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Common (may affect up to 1 in 10 people)
- Feeling restless and not being able to keep still (akathisia)

Rare (may affect up to 1 in 1,000 people)
- You have a very fast or very slow, uneven or forceful heartbeat (cardiac arrhythmia)
- You have tremor, muscle stiffness or slow movements (extrapyramidal disorders)
- You have trembling, muscle spasms or slow movements (extrapyramidal disorders)
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty swallowing.
- You have infection of the mouth, tongue and limbs (tardive dyskinesia).
- You have tremor, stiffness and shuffling (parkinsonism).
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Not known (frequency cannot be estimated from the available data)
- You have problems with any one of your limbs (dystonia)
- You have problems with the muscles in your tongue, mouth, jaw, arms and legs (dyskinesia).

Not known (frequency cannot be estimated from the available data)
- You have problems with any one of your limbs (dystonia)
- You have problems with the muscles in your tongue, mouth, jaw, arms and legs (dyskinesia).

Common (may affect up to 1 in 10 people)
- Feeling drowsy or sleepy

Uncommon (may affect up to 1 in 100 people)
- Breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain.
- You have difficulty swallowing.
- You have tremor, muscle stiffness or slow movements (extrapyramidal disorders)
- You have tremor, stiffness and shuffling (parkinsonism).
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Less common (may affect up to 1 in 1,000 people)
- You have problems with your eye sight or hearing.
- You have problems with your sense of smell.
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Side effects: Common

- You have a life threatening irregular heartbeat (Torsade de pointes)
- 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.
- You have fits.
- You have a high temperature, sweating, stiff muscles, fast heartbeat, fast breathing.
- You have very fast or very slow, uneven or forceful heartbeats.
- You have trembling, muscle spasms or slow movements (extrapyramidal disorders).
- You have tremor, stiffness and shuffling (parkinsonism).
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Side effects: Rare

- You have chest pain and difficulty breathing.
- You have infection of the mouth, tongue and limbs (tardive dyskinesia).
- You have tremor, stiffness and shuffling (parkinsonism).
- You have very fast or very slow, uneven or forceful heartbeats.
- You have difficulty breathing.

Side effects: Not known

- You have problems with any one of your limbs (dystonia)
- You have problems with the muscles in your tongue, mouth, jaw, arms and legs (dyskinesia).

There have been very rare reports of sudden death with sulpiride. There 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.

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 or pharmacist. 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)
- 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 Tablets are lactose, microcrystalline cellulose, 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 Tablets are white, circular tablets marked S200 on one face and CP on the reverse. Sulpiride 400mg Tablets are white, circular tablets marked S400 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: WOHRACK 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 5500 (UK Only). Please be ready to give the following information:

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<th>Product name</th>
<th>Reference number</th>
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<tr>
<td>Sulpiride 400mg Film-Coated Tablets</td>
<td>28631/0182</td>
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This is a service provided by the Royal National Institute of Blind People.

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