Marketing Authorisation Holder and Manufacturer

A colourless to slightly yellow liquid with an odour of lemon and aniseed.

What Sulpiride Rosemont contains

Not known (frequency cannot be estimated from the available data)
- breath enlargement in men
- uncontrollable movements of the mouth, tongue and limbs (tardive dyskinesia)
- tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate antidiuretic hormone secretion (SIADH)
- feeling depressed
- high blood sugar levels (hyperglycaemia)
- high or low body temperature
- blocked nose
- dry mouth
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.
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 diabetes
you have a type of bowel obstruction (ileus)
you have difficulty passing water (urine)
you have a digestive problem called congenital digestive stenosis
you or someone else in your family has a history of breast cancer.
Sulpiride 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 Sulpiride.

Other medicines and Sulpiride

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

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

- Levodopa, used to treat Parkinson’s Disease (sometimes this is called L-dopa).
- Other medicines to treat Parkinson’s Disease including ropinirole and pramipexole
- Medicines to treat high blood pressure or migraine such as beta-blockers, cilnidipine or diuretics which lower potassium levels (water tablets)
- 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.
- Medicines used to treat abnormal heart rhythms (quinidine, disopyramide, amiodarone, sotalol) or antihypertensive agents
- Cisapride and other medicines used to treat stomach problems or laxatives
- Trifluralin used to treat depression
- Some medicines used for allergies (antihistamines that make you sleep) such as chlorphenamine, promethazine, ketotifen.
- Medicines used to help you sleep or lower your anxiety
- Steroids such as prednisolone, dexamethasone and tocopherol.
- Medicines to treat infections such as erythromycin or amoxicillin 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
- Methadone used for addiction and pain relief
- Halofantrine used to treat malaria.

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

Sulpiride with food or drink

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

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): shallowing, 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

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

Sulpiride Rosemont contains methyl and propyl hydroxybenzoates and liquid maltitol. 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 Sulpiride Rosemont

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.

G7BD1RBJ2

**4. Possible side effects**

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Use in children and adolescents:

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

If you take more Sulpiride than you should

If you take more Sulpiride 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

If you forget a dose, skip the missed dose then go on as before.

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

If you stop taking Sulpiride

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.

**Use in other medicines and Sulpiride**

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

In particular,

- medicines used to treat Parkinson’s Disease including ropinirole and pramipexole
- Medicines to treat high blood pressure or migraine such as beta-blockers, cilnidipine or diuretics which lower potassium levels (water tablets)
- 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.
- Medicines used to treat abnormal heart rhythms (quinidine, disopyramide, amiodarone, sotalol) or antihypertensive agents
- Cisapride and other medicines used to treat stomach problems or laxatives
- Trifluralin used to treat depression
- Some medicines used for allergies (antihistamines that make you sleep) such as chlorphenamine, promethazine, ketotifen.
- Medicines used to help you sleep or lower your anxiety
- Steroids such as prednisolone, dexamethasone and tocopherol.
- Medicines to treat infections such as erythromycin or amoxicillin 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
- Methadone used for addiction and pain relief
- Halofantrine used to treat malaria.

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

**Sulpiride with food or drink**

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

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): shallowing, 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

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

Sulpiride Rosemont contains methyl and propyl hydroxybenzoates and liquid maltitol. 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.

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.

G7BD1RBJ2

**4. Possible side effects**

Use all medicines, sulpiride can cause side effects although not everybody gets them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**Use in other medicines and Sulpiride**

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

In particular,

- medicines used to treat Parkinson’s Disease including ropinirole and pramipexole
- Medicines to treat high blood pressure or migraine such as beta-blockers, cilnidipine or diuretics which lower potassium levels (water tablets)
- 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.
- Medicines used to treat abnormal heart rhythms (quinidine, disopyramide, amiodarone, sotalol) or antihypertensive agents
- Cisapride and other medicines used to treat stomach problems or laxatives
- Trifluralin used to treat depression
- Some medicines used for allergies (antihistamines that make you sleep) such as chlorphenamine, promethazine, ketotifen.
- Medicines used to help you sleep or lower your anxiety
- Steroids such as prednisolone, dexamethasone and tocopherol.
- Medicines to treat infections such as erythromycin or amoxicillin 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
- Methadone used for addiction and pain relief
- Halofantrine used to treat malaria.

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

Sulpiride with food or drink

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

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): shallowing, 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

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

Sulpiride Rosemont contains methyl and propyl hydroxybenzoates and liquid maltitol. 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.

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.
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.

3. How to take Sulpiride Rosemont

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.
What Sulpiride Rosemont looks like and contents of the pack

6. Contents of the pack and other information

Common side effects

- yellowing of your skin and whites of the eyes (jaundice), inflammation of your liver (hepatitis)
- skin reaction to sunlight
- difficulty in passing water.

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 rash
- constipation

Uncommon (may affect up to 1 in 100 people)
- breast enlargement in men
- 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 dystokinesia)
- tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- feeling uphill, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- feeling depressed
- high blood sugar levels (hyperglycaemia)
- high or low body temperature
- blocked nose
- dry mouth

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.

Blood tests

Sulpiride 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.

5. How to store Sulpiride Rosemont

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. 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 the expired medicine.
- Get rid of the medicine 3 months after opening.

6. Contents of the pack and other information

What Sulpiride Rosemont contains
- the active ingredient is sulpiride.
- the other ingredients are methyl parahydroxybenzoate (E219), propyl parahydroxybenzoate (E218), propylene glycol (E120), citric acid monohydrate (E330), liquid maltitol (E965), lemon flavour, aniseed flavour and purified water.

What Sulpiride Rosemont looks like and contents of the pack
- A cobalt blue 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, Yardlake Industrial Park, Brighthawke Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 04/2018.