

PACKAGE LEAFLET: INFORMATION FOR THE USER

EGLONYL FORTE

200mg tablets

SULPIRIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

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1. WHAT EGLONYL FORTE TABLETS ARE AND WHAT THEY ARE USED FOR

Eglonyl Forte Tablets contains a medicine called sulpiride. This belongs to a group of medicines called 'benzamides'. It works by blocking the effect of a chemical in the brain. Eglonyl Forte Tablets are used to treat Schizophrenia.

2. BEFORE YOU TAKE EGLONYL FORTE TABLETS

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to sulpiride or any of the other ingredients of Eglonyl Forte Tablets
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a tumour on the adrenal gland called 'phaeochromocytoma'
- You have a rare illness called 'porphyria' which affects your metabolism
- 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 Eglonyl Forte Tablets.

Take special care with Eglonyl Forte Tablets

Check with your doctor or pharmacist before you take this medicine if:

- You have bouts of aggressive behaviour or are very agitated
- You have kidney problems
- You have heart problems or a family history of heart problems. Your doctor may test your heart function before you take this medicine
- You have ever had a stroke
- If 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 low levels of potassium in your body (hypokalaemia)
- The person is 65 years of age or older
- You have dementia
- You have Parkinson's disease
- You have low blood levels of potassium, calcium and magnesium. Your doctor may do blood tests to check on these
- You have epilepsy or have had fits (seizures)
- You have a low number of white blood cells (agranulocytosis). This means you may get infections more easily than usual
- You have frequent infections such as fever, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called 'leukopenia'
- You have high blood pressure
- You have painful eyes with blurred vision (glaucoma)
- You have a type of bowel obstruction (ileus)
- You have difficulty passing water (urine)
- You have an enlarged prostate
- You have a digestive problem called congenital digestive stenosis

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Eglonyl Forte 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 Eglonyl Forte Tablets can affect the way some other medicines work. Also some medicines can affect the way Eglonyl Forte works.

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

- Levodopa used for Parkinson's disease

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

- Medicines to control your heartbeat such as amiodarone, sotalol, disopyramide or quinidine
- Medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or digitalis
- 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 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
- 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 sleepy) such as chlorphenamine, promethazine, ketotifen
- Ropinirole used for Parkinson's disease
- Methadone used for pain relief and as a drug substitute
- Halofantrine used for malaria

Taking Eglonyl Forte Tablets with food and drink

Do not drink alcohol or take medicines that contain alcohol while being treated with Eglonyl Forte Tablets. This is because alcohol can increase the effects of Eglonyl Forte Tablets.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before having this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Do not breast-feed if you are taking Eglonyl Forte Tablets. This is because small amounts may pass into mothers' 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 Eglonyl Forte 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

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

Important information about some of the ingredients of Eglonyl Forte Tablets

- Lactose. Eglonyl Forte Tablets contain lactose. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Eglonyl Forte tablets

3. HOW TO TAKE EGLONYL FORTE TABLETS

Always take Eglonyl Forte Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink 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

How much to take

Adults

- The usual starting dose is 400mg (two 200mg tablets) to 800mg (four 200mg tablets) daily depending on your illness.

- Your doctor may then change your dose depending on your illness
- Patients with Kidney Disease
- The starting dose may be lower and the rate of increasing the dose slower.

Children under 14 years of age

Eglonyl Forte Tablets are not recommended for children under 14 years of age.

If you take more Eglonyl Forte Tablets than you should

If you take more Eglonyl Forte 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 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 Eglonyl Forte Tablets

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

If you stop taking Eglonyl Forte Tablets

Keep taking Eglonyl Forte Tablets until your doctor tells you to stop. Do not stop taking Eglonyl Forte Tablets just because you feel better. If you stop taking Eglonyl Forte 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, Eglonyl Forte Tablets can cause side effects, although not everybody gets them.

Stop taking Eglonyl Forte 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 Eglonyl Forte. 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

Eglonyl Forte 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE EGLONYL FORTE TABLETS

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Eglonyl Forte Tablets after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Store below 25°C

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.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in 01/2016