

PACKAGE LEAFLET: INFORMATION FOR THE USER

Δ Eglonyl

25 mg/5 ml oral solution

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?

1. What Eglonyl is and what it is used for
2. Before you take Eglonyl
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1. WHAT EGLONYL IS AND WHAT IT IS USED FOR

Eglonyl solution contains sulpiride which belongs to a group of medicines called antipsychotics. It acts on the brain to calm the patient who is restless and returns it to its normal mood.

Eglonyl solution is used:

- for the short term treatment of anxiety in adults, when the answer to the usual treatment is not sufficient and
- for the treatment of behavioral disorders (agitation, self-harming behavior, stereotyped behavior), in children who are older than six years, particularly those with autism.

2. BEFORE YOU TAKE EGLONYL

Do not take Eglonyl:

- if you are allergic (hypersensitive) to sulpiride or any of the other ingredients of the medicine,
- if you are taking medicine for Parkinson's disease called levodopa,
- if you have ever had cancer of the breast or pituitary prolactin (a type of brain tumor),

- if you have adrenal tumor called pheochromocytoma and
- if you have a rare disease called Porphyria, which affects the metabolism.

Be careful with the Eglonyl if:

- you are pregnant, planning a pregnancy, or if you are breastfeeding,
- have hypomania - mood swings that can be displayed as excitement, anger, irritability and decreased need for sleep,
- you are having problems with the kidneys,
- you have heart problems or family history of heart problems. A doctor can test the functionality of your heartbeat before taking this medicine,
- you have ever had a stroke,
- you have low potassium levels in the body (hypokalaemia),
- you have 65 years or more,
- you have dementia,
- you have Parkinson's disease,
- you have low levels of potassium, calcium and magnesium in the blood. A doctor may do tests to check Your blood,
- you have epilepsy or are there when you have cramps (attacks) and
- you have diabetes.

Taking other medicines with Eglonyl

Please tell your doctor or pharmacist about all medicines you are taking or have recently taken, including those obtained without a prescription or herbal medicines.

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

- levodopa-medicine used for Parkinson's disease. If you are taking levodopa you may not take Eglonyl.

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

- medicines to control heart rate, such as amiodarone, sotalol, disopyramid or hinidin,
- medicines for high blood pressure or heart disorders, such as clonidine, diltiazem, verapamil or digitalis,
- other medicines for schizophrenia as pimozide, haloperidol, tioridazin,
- lithium-that is used for some types of mental illness,
- medication to help you sleep better or that reduces anxiety,
- other medicines to calm emotional and mental problems,
- medicines for urination (diuretics), which can lower your potassium levels in the blood,
- some medicines used for constipation (laxatives) which can lower your potassium levels in the blood,
- some medicines used for infections (antibiotics), pentamidine, erythromycin, or amphotericin B,
- tetracosactides - that are used for testing the function of the adrenal glands,
- steroids-that are used to reduce inflammation, such as prednisolone, betamethasone, dexamethasone,
- some medication for depression, such as imipramine,
- medicines for indigestion and heartburn,
- sucralfate-used for ulcers on the stomach,
- medication for pain relief. It also can be found in the medication for a cold and the flu,
- individual medicines used for allergies (antihistamines which have a hypnotic effect), such as chlorphenamine, promethazine, ketotifen,
- ropinirol-used for Parkinson's disease,
- methadone-which is used to relieve pain and as a medicine replacement and
- halofantrine-that is used for malaria.

Food and drinks

Do not drink alcohol or take medicines containing alcohol while you are being treated with Eglonyl. That's because alcohol may increase the effects of Eglonyl solution.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before you begin to use any medicine.

Eglonyl must not be used during pregnancy and lactation.

Driving and using machines

Δ Trigonon, a medicine with the possible influence on the psychophysical abilities (warning related to driving and using machines).

What you need to know about other substances that Eglonyl contains

Eglonyl oral solution contains Methylparahydroxybenzoate E218 and propyl parahydroxybenzoate E216 which may cause allergic reactions (possibly delayed hypersensitivity reactions).

Eglonyl oral solution also contains the color E102 which may cause allergic-type reactions.

3. HOW TO TAKE EGLONYL

Always take Eglonyl as instructed by your doctor. If you are not sure, consult with your doctor or pharmacist.

The recommended doses of Eglonyl are:

Adults

For the short-term treatment of anxiety, when the answer to the usual treatment is not sufficient:

100 mg to 200 mg per day with a maximum duration of therapy of four weeks.

A special case of ulcer disease:

Oral maintenance therapy is three solution of 50 mg a day for four to six weeks.

Children older than six years

For the treatment of behavioral disturbances (agitation, self-harming behavior, stereotypic behavior), especially in autism: 5 mg / kg / day (the dose may be increased to 10 mg / kg / day).

If you take more Eglonyl solution than you should

If you have taken a higher dose than you should, tell your doctor right away or go to the nearest health care facility. Take the packaging of the medicine with yourself. It is necessary to make a doctor know what you have taken.

You may experience the following symptoms: a feeling of restlessness, confusion or nervousness, decreased level of consciousness, tremor, muscle stiffness and spasms, difficulty in movement, movements that cannot be controlled (e.g., eyes, neck, hands and legs), the creation of more saliva than normal. In some cases a light-headedness, dizziness or fainting (low blood pressure) and coma may occur.

If you forget to take Eglonyl solution

Never take a double dose to replace the missed dose of the medicine.

If you accidentally miss the daily dose, just take the next dose at the usual time.

If you stop taking Eglonyl solution

Continue taking Eglonyl solution until your doctor tells you to stop. Do not stop taking the medication, even if you feel better. If you suddenly stop taking the Eglonyl, your disease may come back and you can have other side effects such as feeling sick, excessive sweating or trouble sleeping. In some cases, you may feel discomfort

or have movements that you cannot control (for example, eyes, neck, arms and legs). Your doctor will gradually reduce the dose of your medicine, in order to prevent the occurrence of these side effects.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Eglonyl can cause side effects, although not everybody gets them. Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

You must stop using the Eglonyl if you:

- have an allergic reaction. Signs may include: rash, itching, fever, difficulty in breathing or chest pains, tremors, swelling,
- have movements that you cannot control, mainly of the tongue, lips, jaw, hands and feet,
- cramping,
- have high fever, sweating, muscle stiffness, fast heartbeat, rapid breathing and if you feel confused, sleepy or upset. These may be signs of a serious but rare side effect called neuroleptic malignant syndrome and
- have very fast or very slow, uneven or strong heartbeat. You can also have trouble breathing, such as wheezing, shortness of breath, chest tightness and pain in the chest.

Tell your doctor as soon as possible, if you have any of the following side effects:

- light-headedness, dizziness or fainting when standing or sitting (low blood pressure),
- stiff or uptight muscles, tremors or shaking, difficulty in movement,
- feeling restless and you can't stand still (akathisia) and
- feeling aggressive, anxious or impulsive.

Talk to your doctor or pharmacist if any of the following side effects become severe or last longer than a few days:

- abnormal breast milk production in both men and women,
- weight gain,
- breast enlargement or sore breasts in men and women,
- loss of menstrual periods,
- problems with erection or keeping erections or ejaculation (impotence),
- feeling sleepy,
- difficulty sleeping (insomnia) and
- skin rashes.

Blood tests

Eglonyl solution may increase the level of liver enzymes that appear in blood tests. It may mean that your liver is not working properly.

Talk to your doctor or pharmacist if you notice that a side effect of the medicine has become serious or lasts longer than a few days, or if you notice any side effect that is not specified in this leaflet.

Very rare cases of sudden death were reported with Eglonyl solution, probably caused by heart problems.

If you notice any side effects please tell your doctor or pharmacist.

5. HOW TO STORE EGLONYL

Keep out of reach and sight of children.

Eglonyl must not be used after the expiration date stated on the carton. Expiration date refers to the last day of that month.

The product should be stored at temperature below 30 °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.

6. FURTHER INFORMATION

What Eglonyl contains

- The active substance is sulpiride.
- 5 ml oral solution contains 25 mg of sulpiride.
- Excipients: Methyl E218; Propyl E216; sorbic acid; sodium saccharin; hydroxyethylcellulose; citric acid monohydrate chloride acid; colors lemon-yellow (E102); lemon flavor; Purified water

How Eglonyl looks like and contents of the pack

Eglonyl oral solution is pale yellow, non-viscous liquid with a faint scent of lemon.

Oral solution is packed in a dark brown bottle of neutral glass and plastic cap.

The box contains 1 glass bottle (120 ml oral solution) and plastic dispenser 2.5 ml, 20 ml, with attached instructions.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

ALKALOID AD – Skopje, (in cooperation with Sanofi-Aventis)
Bulevar Aleksandar Makedonski 12, Skopje, Republic of Macedonia

Manufacturer of the medicinal product

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Bulevar Aleksandar Makedonski 12, Skopje, Republic of Macedonia