PACKAGE LEAFLET: INFORMATION FOR THE USER

REDERGIN

1.5 mg tablets; 4.5 mg tablets; 1 mg/mL oral solution

ERGOLOID MESYLATE

• 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 REDERGIN IS AND WHAT IT IS USED FOR

Redergin belongs to a group of medicines that improve blood flow, especially to the brain. As a result of its action, it improves the ability of perception, memory and concentration. Redergin also acts on mood and feelings.

Redergin is intended for:

- improving brain cell activity, especially in older people
- symptomatic treatment of changes made after stroke

2. BEFORE YOU TAKE REDERGIN

Alert the doctor if you are taking other medicines, you have a chronic disease, a metabolic disorder, hypersensitive you are on medication or have had an allergic reaction to some of them.

Do not take Redergin:

- you are allergic (hypersensitive) to dihydroergotoxine mesylate or any of the other ingredients of medicinal product
- you have a slow heart rate (less than 40 to 50 beats per minute)
- you have low blood pressure
- you will be treated with Redergin for a long period of time and you have or have had changes of fibrous (scar tissue) that is on your heart.

Be especially careful when taking Redergin:

- If you have or have had changes of fibrous (scar tissue) that is placed on your heart, lungs, or abdomen. If you are being treated with Redergin for a long period of time, your doctor will check the general condition of the heart, lungs and kidneys. He/she will do an Echocardiogram (heart ultrasound) before the start of treatment. Also, during treatment, your doctor will pay attention to any sign that could be caused by fibrous changes. And in this case, doctor may propose an echocardiogram of the heart. In case of fibrous change the treatment should be stopped.
- If you are using medicines for lowering blood pressure
- If you have Porphyria (a metabolic disorder caused by a lack of the enzyme)
- If you have impaired kidney function
- If you have a diseased blood vessels

Please tell your doctor about all of the listed conditions, even if you had them in the past.

Taking other medicines

Tell your doctor or pharmacist if you are taking other medicines or have recently used them even if these medicines can be bought without prescription.

Taking Redergin with food and drink

Food has no significant effect on the absorption of the medicine.

Pregnancy and breastfeeding

Before you start taking any medication, consult with your doctor or pharmacist.
Effect of Redergin on the fetus or infant is unknown. Please tell your doctor if you are pregnant while taking this medicine. Your doctor will decide whether to use this medicine during pregnancy and breastfeeding or not.

Ability to drive and use machines

There is no information available to suggest that the correct application of Redergin causes effect on the ability to drive and use machines.

Important information about some of the ingredients of Redergin

Redergin tablets:
This medical product contains lactose monohydrate.
Each tablet contains 0.1 g of lactose monohydrate. With each daily dose you take up to 0.3 g of lactose monohydrate.
If your doctor said that you have intolerance to some sugars, contact him before using Redergin.
Redergin oral solution:
Redergin oral solution contains vol. 6.2% (V/V) alcohol, IE. up to 0.05 g per dose of 20 drops, corresponding to 63 ml of beer or 26 ml of wine in a single dose. Therefore, this product is harmful to patients who have problems associated with alcoholism.
Content of ethanol (alcohol) present in Redergin have to be taken into account when this medicine is given to pregnant women, nursing mothers, children and high-risk patients such as those with hepatic impairment or epilepsy.
Redergin may emphasize the action of other medicines.

3. HOW TO TAKE REDERGIN

Always take Redergin exactly as your doctor has told you. You need to check with your doctor or pharmacist if you are not sure.

You are not permitted to change the dosage or discontinuing the use of the medicine without consulting your doctor, who will determine the dosage and duration of treatment.
Treatment with Redergin is prolonged; the best effect of the medicine is achieved after six to twelve weeks.

Take this medicine after meals.
Usual dosage:
Redergin 1.5 mg tablets: 3 times a day (morning, day and night)
Redergin 4.5 mg tablets are taken once a day (at any time of the day).
The usual dosing with Redergin oral solution is 30 to 40 drops of solution (1 mg/1 ml) 3 times a day (morning, day and night).
In the case of more serious forms of the disease, your doctor may increase your dose.
You should use Redergin as long as your doctor prescribed.

If you have taken more Redergin than you should

The level of safety in the event of an overdose with Redergin is high. There are no known cases of poisoning with this medicine.
If you take more medicine than you should, it is recommended that you seek medical attention as soon as possible.

If you forget to take Redergin

If you forget to take Redergin take it as soon as you remember. If it is almost time for your next dose, take it at the usual time and skip the missed dose.
Do not take a double dose to make up for a missed dose.

If you interrupt the treatment with Redergin

Do not stop the treatment. Contact your doctor or pharmacist before the interruption of treatment.
If you have any further questions about this product, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Redergin may cause side effects, although not everybody gets them.

This medicine is generally well tolerated. Most of the side effects that occur are mild and transient.

Assessment of the frequency of side-effects is based according to the frequency of occurrence:

Very common	Appear in more than 1 in 10 patients
Common	Appear at 1 to 10 patients on 100 patients
Uncommon	Appear at 1 to 10 patients on 1000 patients
Rare	Appear at 1 to 10 patients on 10000 patients
Very rare	Appear at fewer than 1 patient in the 10000 patients
Unknown frequency	Not possible to evaluate from available data

Very rare side effects (occurs in less than 1 out of 10000 patients treated) are damaging the heart valve and similar disorders such as eg. inflammation of the lining of the heart (pericarditis), effusion of fluid in the lining

of the heart (pericardial effusion). Early symptoms of the condition can include difficulty in breathing, shortness of breath, chest pain or back pain and leg swelling.
If you notice any of the above symptoms, please urgently contact your doctor.

Other possible side effects:
Common (1 to 10 of 100 patients treated with people)
Nausea, vomiting, loss of appetite, stomach tension

Uncommon (1 to 10 of 1000 patients treated with people)
Dizziness, hyperactivity, slowed heart operation, clogged nose

Rare (1 to 10 of 10000 patients treated with people)
A rash on the skin

Unknown (cannot be estimated on the basis of the available data)
Blurred vision, orthostatic hypotension (excessive reduction in blood pressure when standing up, can cause unconsciousness)

These side effects usually do not require treatment discontinuation.

If any of the side effects worsen or you notice side effects that are not specified in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE REDERGIN

Keep the medicine out of reach and sight of children.
Store below 25 □ C, protected from light.
Shelf life: 2 years.
Do not use the medication after the expiration date that is specified on the box. The expiration date refers to the last day of the month.
Do not use this medicine if you notice any sign of damage.

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 Redergin contains

The active substance is in the form of mesylate ergoloid dihydroergotoxine methanesulphonate.
Ergoloid mesylate (dihydroergotoxine methanesulphonate) consists of:

- Dihydroergocristine methanesulfonate
- dihydroergocornine methanesulfonate
- dihydroergocryptine methanesulfonate
- Relation between β and α dihidroergokristin methanesulfonate is (1.5 - 2.5): 1.0.

Redergin 1.5 mg tablets
Each tablet contains 1.5 mg of ergoloid mesylate in the form of dihydroergotoxine methanesulphonate.
Redergin 4.5 mg tablets
Each tablet contains 4.5 mg of ergoloid mesylate in the form of dihydroergotoxine methanesulphonate.
Redergin 1 mg/mL oral solution

Every ounce of oral solution (20 drops) contains 1 mg of ergoloid mesylate in the form of dihydroergotoxine methanesulphonate.

Auxiliary substances
Redergin 1.5 mg tablets
Corn starch, monohydrate lactose, mannitol, crospovidone, povidone, talc, Stearic acid, hydrogenated vegetable oil.
Redergin 4.5 mg tablets
Erythrosine (E127), corn starch, monohydrate lactose, mannitol, crospovidone, povidone, talc, Stearic acid, hydrogenated vegetable oil.
Redergin 1 mg/mL oral solution
butylhydroxyanisole, ethanol 6.2% vol. glycerol, glycine, methanesulfonic acid (for pH adjustment), purified water.

Pharmaceutical form and contents of the Pack
Redergin 1.5 mg tablets are white, round, flattened tablets with dividing line on one side and a large letter "R" on the other side. Tablets are in blister packaging, foil (aluminium and PVC-and-PVDC) box with 20 tablets (2 x) with 1.5 mg also as mesylate.
Redergin 4.5 mg tablets are red, round, flattened tablets with dividing line on one side and a large letter "R" on the other side. tablets are in blister packaging, foil (aluminium and PVC-and-PVDC) box with 20 tablets (2 x) with 4.5 mg also as mesylate.
Redergin 1 mg/ml oral solution is a colorless to slightly yellowish clear solution.
A box with a vial (brown glass hydrolytic resistance class III and Red-Brown lid) that contains 50 ml oral solution 1 mg/ml also as mesylate and graded dropper.

Regime of dispensing
The medicine is issued on doctor's prescription

Manufacturer
LEK farmacevtska družba d.d.
Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product
LEK farmacevtska družba d.d.
Verovškova 57, Ljubljana, Slovenia