**APPROVED**

**by the Order of the Ministry of Health of Ukraine**

**04.09.2020 No. 2032**

**Marketing Authorization**

**No. UA/18282/01/01**

**PACKAGE LEAFLET**

**for medical use of a medicinal product**

**Glycine-Darnitsa**

***Qualitative and quantitative composition:***

*active substance:* glycine;

1 tablet contains glycine (on a 100% dry substance basis) 100 mg;

*List of excipients:* povidone, ammonium methacrylate copolymer dispersion (type A), ammonium methacrylate copolymer dispersion (type B), magnesium stearate.

**Pharmaceutical form.** Sublingual tablets.

*Main physical and chemical properties:* tablets of white or almost white color, flat-cylindrical shape with a bevel and a dash.

**Pharmacotherapeutic group.** Other nervous system drugs. ATC code N07ХХ.

***Pharmacological properties.***

*Pharmacodynamic properties.*

Glycine (aminoacetic acid) has the properties of a regulator of metabolism and is a substitute amino acid (natural metabolite), is a neurotransmitter of the inhibitory type of action and a regulator of metabolic processes in the central nervous system.

The medicinal product has glycine and GABA-ergic, α-adrenoblocking, antioxidant, antitoxic effect, regulates the activity of glutamate receptors, due to which it is able to:

- to reduce psycho-emotional stress, aggression, conflict, to increase social adaptation;

- improve mood;

- facilitate falling asleep and normalize sleep;

- improve mental performance;

- to reduce vegetative-vascular disorders, including during menopause;

- to reduce the severity of cerebral disorders in ischemic stroke and traumatic brain injury;

- to reduce the toxic effects of alcohol.

The medicinal product is not addictive.

Pharmacokinetic properties.

Easily penetrates into biological fluids and body tissues, including the brain. It is rapidly destroyed in the liver by glycine oxidase to water and carbon dioxide. The accumulation of glycine in the tissues does not occur.

**Clinical particulars.**

***Therapeutic indications.***

Decreased mental performance.

Stressful situations and psycho-emotional stress (during exams, in conflict situations).

Deviant forms of behavior of children and adults.

Functional and organic diseases of the nervous system (neuroses, neurosis-like states, vegetative-vascular dystonia, the consequences of neuroinfection, traumatic brain injury, perinatal and other forms of encephalopathy, including alcoholic genesis), which are accompanied by increased excitability, emotional instability, decreased mental performance, sleep disturbances.

Ischemic stroke and cerebrovascular disorders.

As an adjuvant in the treatment of alcoholism.

***Contraindications.***

Individual intolerance to the medicinal product and hypersensitivity to its individual components; arterial hypotension. Children age up to 3 years.

***Interaction with other medicinal products and other forms of interaction.***

Glycine-Darnitsa reduces the toxicity of anticonvulsants, antipsychotics, antidepressants, antiepileptic medications. When combined with hypnotics, tranquilizers and antipsychotics, the effect of inhibition of the central nervous system is enhanced.

***Special warnings and precautions for use.***

In patients with a tendency to arterial hypotension, it is necessary to monitor the level of blood pressure and, if necessary, adjust the dose of the medicinal product. Glycine is prescribed in smaller doses and subject to regular monitoring of blood pressure. When it drops below the usual level, the use of the medicinal product is discontinued.

*Fertility, pregnancy and lactation.*

The effect of glycine on the body during pregnancy and lactation has not been studied in detail, so administration of medicinal product is not recommended.

*Effects on ability to drive and use machines.*

Care must be taken during driving or use machines, as well as with potentially hazardous activities.

***Posology and method of administration.***

The medicinal product is used transbuccally or sublingually (in tablets or in powder form after grinding the tablet).

*Children over 3 years of age, adolescents, adults* with a decrease in mental performance, memory, attention, with mental retardation, with psycho-emotional stress, with deviant forms of behavior Glycine-Darnitsa is prescribed 1 tablet (100 mg) 2–3 times a day for 14-30 days.

The maximum daily dose is 300 mg.

*Children over 3 years of age and adults* with functional and organic diseases of the nervous system (neuroses, neurosis-like states, vegetative-vascular dystonia, consequences of neuroinfection, traumatic brain injury, perinatal and other forms of encephalopathy, including the number of alcoholic genesis) is prescribed 1 tablet 2-3 times per day, the course of treatment is 7-14 days. Repeat the course of treatment if necessary.

*For sleep disorders,* 50-100 mg is prescribed 20 minutes before bedtime or just before bedtime.

*For ischemic stroke and cerebrovascular disorders* 1 g of the medicinal product is prescribed transbuccally or sublingually (if necessary, grind the tablet) for the first 3-6 hours after the onset of stroke, then - for 1-5 days, 1 g per day, then for 6- 30 days - 1-2 tablets 3 times per day.

*In the treatment of alcoholism,* the medicinal product is prescribed as an adjuvant to 1 tablet 2-3 times per day for 14-30 days. If necessary, the course of treatment is repeated 4-6 times a year.

*Children.*

The medicinal product is used in children over 3 years old.

***Overdose.***

There are no data on clinical manifestations of overdose.

***Undesirable effects.***

The medicinal product is usually well tolerated. In some cases, with individual hypersensitivity, allergic reactions may develop, including rhinitis, conjunctivitis, rash, itching, urticaria, irritation (perspiration) in the throat, weakness.

On the part of the gastrointestinal tract, dyspeptic symptoms may develop, including epigastric pain, nausea. On the part of the nervous system, isolated cases of deterioration in concentration, headache, tension, irritability were observed.

***Shelf life.*** 1,5 years.

**Special precautions for storage.**

Store in the original package at a temperature below 25°C.

Keep out of the reach of children.

**Nature and contents of container.**

10 tablets in a blister container; 3 or 6 blister containers in a package.

**Category of release.** Non-prescription medicine.

**Manufacturer.** PrJSC “Pharmaceutical firm “Darnitsa”.

**The manufacturer's location and address of the place of business.**

13, Boryspilska Street, Kyiv, 02093, Ukraine.

**Date of last revision.** 04.09.2020.