Deltaran®

INTERNATIONAL NON-PROPRIETARY NAME (INN): Deltaran

DOSAGE FORM AND STRUCTURE:
Composition (1 ampoule):
Active ingredient: tryptophanyl-alanyl-glycyl-glycyl-aspartyl-alanyl-seryl-glycyl-glutamic acid (delta-sleep peptide) - 0.3 mg.
Excipient: glycine - 3.0 mg.

DESCRIPTION: Lyophilisate in ampoules in the form of powder or porous mass of white color for the preparation of a solution for intranasal administration. 5 ampoules in a cassette blister strip package. One cassette blister strip package contains the description and a pipette in a cardboard pack.

ATC CODE: N07BB Drugs used in alcohol dependence.

PHARMACOLOGICAL ACTION: Treatment of alcohol withdrawal.

PHARMACODYNAMICS:
The active substance of **Deltaran**® is a synthetic nonapeptide, similar in structure to the endogenous substance of the human body. This peptide is present both in the body of every person and in the organisms of other mammals. Therefore it does not exhibit any toxic properties.
The synthesized peptide is completely identical to the natural peptide produced in the body and known as the delta-sleep peptide which has a wide spectrum of pharmacological action: neuroprotective, antistress, antioxidant, anticonvulsant, antihypoxic, antitoxic and geroprotective. Once in the body, the exogenous delta-sleep peptide replenishes the deficiency of the endogenous peptide, absolute or functional, which allows the control neurons to work most adequately under stress conditions of any kind and to prevent the occurrence of metabolic deviations from physiological norms.
Deltaran® reduces the pathological alcohol addiction and eliminates manifestations of alcohol withdrawal.

PHARMACOKINETICS:
The components of the drug are non-specifically transported through the blood-brain barrier and are distributed in the human body within 120 minutes approximately as follows: 80% - the liver, 15% - the brain, 5% - the peripheral blood (after exiting the blood-brain barrier, the drug components bind to blood transport proteins and are detected immunochemically in peripheral blood within 1.5 -2 hours). The drug is non-toxic and does not accumulate in the body.

INTENDED USES:
As part of the complex therapy (including psychotherapy):
- Alcohol withdrawal syndrome and primary pathological alcohol addiction;
- Treatment and prevention of stress-induced conditions.

CONTRAINDICATIONS:
Hypersensitivity, pregnancy, the period of breastfeeding, the age under 18 y.o.

DOSAGE AND ADMINISTRATION:
Immediately prior to use **Deltaran**® is dissolved in 0.2-0.5 ml of boiled water of room temperature and 0.1-0.3 ml of the solution is pipetted into each nasal passage. The solution is utilized in full and cannot be stored. The pipette must be washed thoroughly with boiled water after every use.
Depending on the severity of the disease, adults use 1-3 ampoules per

day for 5-10 days. The course of treatment can be repeated if necessary after 4-8 weeks.
The optimal dosage regimen is determined by the doctor.

PRECAUTION:
In case of inflammatory nose diseases (acute rhinitis), the drug absorption efficiency of the mucous membrane can be reduced. In such cases, it is recommended to administer the drug after the nasal rinsing or after removing nasal stuffiness with other medications.
It is not recommended to use the drug in case of severe bradycardia, as well as in case of individual intolerance.
In severe conditions (alcohol withdrawal), you must consult a doctor for prescribing additional detoxification drugs.

SIDE EFFECTS:
Allergic reactions and irritation of the nasal mucosa are possible.

OVERDOSE:
Cases of overdose have not been reported.

INTERACTION WITH OTHER DRUGS:
Pharmacological incompatibility with other drugs has not been identified.

PREGNANCY AND LACTATION:
The drug is contraindicated during pregnancy and lactation (breastfeeding).

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
The drug does not affect the ability to drive vehicles and operate moving mechanisms.

STORAGE CONDITIONS:
Store in a dark place, at a temperature from 2 °C (35.6 °F) to 15 °C (59 °F). Keep out of the reach of children.

SHELF LIFE: 3 years. Do not use beyond the expiration date.

MANUFACTURER: Federal State Unitary Enterprise "State Research Institute of High Purity Preparations" of the Federal Medical-Biological Agency of Russia (FGUP "Gos.NII OChB" FMBA of Russia) www.hpb-spb.com/en