Semax®

INTERNATIONAL NON-PROPRIETARY NAME (INN): methionyl-glutamyl-histidyl-phenylalanil-prolyl-glycyl-proline.

DOSAGE FORM: nasal drops 0.1% (3 ml).

STRUCTURE:
Nasal drops 0.1%:
Active substance: Semax in terms of 100% substance - 1 g;
Excipients: methyl parahydroxybenzoate (Nipagin) - 1 g, purified water up to 1 l.

Nasal drops 1%:
Active substance: Semax in terms of 100% substance - 10 g;
Excipients: methyl parahydroxybenzoate (Nipagin) - 1 g, purified water up to 1 l.

DESCRIPTION: colourless transparent liquid.

PHARMACOLOGICAL CLASSIFICATION: nootropics.

ATC CODE: N06BX.

PHARMACOLOGICAL ACTION: nootropic, antioxidant, antihypoxic, cerebroprotective.

PHARMACODYNAMICS:
Semax nasal drops have an original mechanism of neuro-specific action on the central nervous system (CNS). Semax drops are a nasal synthetic analogue of Corticotropin; it has nootropic properties and is completely devoid of hormonal activity. The drug has an influence on the processes associated with the formation of memory and learning. Semax nasal drops increase attention during the learning process and the analysis of information. The drug enhances the consolidation of the memory trace in patients after neurosurgical interference, craniocerebral injury and in patients suffering from cerebrovascular diseases, including dyscirculatory encephalopathy; it improves the body adaptation to hypoxia, cerebral ischemia, anesthesia and other damaging effects. The drug is almost non-toxic both in a single and in prolonged administration. It does not demonstrate allergic, embryo-toxic, teratogenic and mutagenic properties. It does not have a local irritative effect.

PHARMACOKINETICS:
Semax is absorbed from the nasal mucosa. At least 60-70% of the active substance is absorbed. Semax is quickly distributed into all organs and tissues and penetrates through the blood-brain barrier. When it gets into the blood, Semax undergoes a rapid biotransformation and excretion from the body with urine.

INTENDED USES:
Nasal drops 0.1%:
- Intellectual and mnestic (memory, attention) disorders;
- States after a traumatic brain injury, neurosurgical operations and narcosis;
- Dyscirculatory encephalopathy;
- Transient cerebrovascular disorders (TIA);
- Neurotic disorders of various genesis, including ones after ionizing radiation;
- Recovery period after a stroke;

- Enhancement of the body adaptation in extreme situations; prevention of mental fatigue during monotonous operator activity and work under stressful conditions;
- In ophthalmology: optic nerve atrophy, neuritis of inflammatory and toxic-allergic etiology;
- In paediatrics: as a nootropic in children from the age of 7 years old, in the treatment of the minimal brain dysfunction (including ADHD - attention deficit hyperactivity disorder).

Nasal drops 1%:
- Acute period of moderate to severe ischemic stroke as part of the complex therapy.

CONTRAINDICATIONS:
- Hypersensitivity to the components of the drug;
- Children under 7 y.o. In ophthalmic and neurosurgical practice, children under 18 y.o. (no clinical studies have been conducted);
- Pregnancy and lactation (no clinical studies have been conducted).
- Acute psychotic states, disorders accompanied by anxiety;
- History of cramps.

SIDE EFFECTS:
Prolonged use may cause a mild irritation of the nasal mucosa.

DOSAGE AND ADMINISTRATION:
Semax is applied intranasally using a bottle with a plastic pipette stopper.
One drop of the standard solution contains 50 mcg (Nasal drops 0.1%) / 500 mcg (Nasal drops 1%) of the active substance.
Drug solution is pipetted into each nasal passage in the amount of not more than 2-3 drops. If it is necessary to increase the dosage, the instillation is carried out in several doses at intervals of 10-15 minutes.

Nasal drops 0.1%
- **In intellectual-mnestic disorders in case of vascular brain lesions, in dyscirculatory encephalopathy and in transient cerebrovascular disorders:** a single dose is 200 - 2,000 mcg (based on 3 - 30 mcg / kg). The daily dose is 800-8,000 mcg (based on 7-70 mcg / kg). The drug is prescribed in the amount of 2-3 drops in each nasal passage 4 times a day for 10-14 days. If necessary, repeat the treatment.
- **After a traumatic brain injury, neurosurgical operations and anesthesia**: a single dose is 1,400 - 3,500 mcg (40-50 mcg / kg) 3 times a day for 3 to 5 days. If necessary, the course of treatment is extended to 14 days.
- **To increase the adaptive capabilities of the human body and the prevention of mental fatigue:** 2-3 drops in each nasal passage 2-3 times in the first half of the day for 3-5 days. The daily dose is 400-900 mcg / day. If necessary, repeat the treatment.
- **In diseases of the optic nerve**: 2-3 drops in each nasal passage 2-3 times a day. The daily dose is 600-900 mcg / day. The course of treatment is 10 days. In addition, the drug can be administered by endonasal electrophoresis. The drug is injected from the anode. The current strength is 1 mA, the exposure time is 8-12-15 minutes. The daily dose is 400-600 mcg / day. The course of treatment is 10 days.
- **In paediatrics:** in children from 7 years old. With minimal cerebral dysfunctions: 1-2 drops in each nasal passage (5 - 6 mcg / kg) 2 times a day (morning and afternoon). The daily dose is 200-400 mcg / day. The course of treatment is 30 days.

Nasal drops 1%
- **In a moderate stroke**: 2-3 drops into each nostril at one time, which is from 2,000 mcg (4 drops or 0.2 ml) to 3,000 mcg (6 drops or 0.3 ml). The instillation is carried out 3-4 times a

day, with an interval between instillations from 3 to 4 hours. The daily dose is 6,000 mcg (12 drops or 0.6 ml) - 12,000 mcg (24 drops or 1.2 ml). The duration of treatment is 10 days.

- **In a severe stroke:** 3-4 drops are injected into each nostril at one time, which is 3,000 mcg (6 drops or 0.3 mg) - 4,000 mcg (8 drops or 0.4 ml). The instillation is carried out 4-5 times a day with an interval between instillations of 2.5-3 hours. The daily dose is 12,000 mcg (24 drops or 1.2 ml) - 20,000 mcg (40 drops or 2.0 ml). The duration of treatment is 10 days.

OVERDOSE:
No symptoms of overdose have been recorded even after a significant dose increase.

INTERACTION WITH OTHER DRUGS:
Pharmaceutically. Based on the chemical structure of the drug, the presence of chemically incompatible combinations is not expected: the drug is rapidly destroyed and does not enter the gastrointestinal tract.
Pharmacokinetically. Given the chemical structure of the drug (heptapeptide is a synthetic analogue of adrenocorticotropic hormone, completely devoid of hormonal activity), the rate of absorption and the rate of entry into the blood, as well as the intranasal route of administration, no effect of other drugs on the pharmacokinetic parameters of Semax is expected. Given the route of administration of Semax (intranasal), the intranasal administration of agents with a local vasoconstrictor effect is undesirable.

PREGNANCY AND LACTATION:
Contraindicated during pregnancy and lactation.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND MECHANISMS:
MACHINES: no data are available.

STORAGE CONDITIONS:
Store in a dark place, at temperatures not exceeding 10 ° C (50 ° F), do not freeze. Keep out of the reach of children.

SHELF LIFE: 2 years. Do not use beyond the expiration date.

COUNTRY OF MANUFACTURE: CJSC "Innovation Research and Production Center "Peptogen", Russia.