Retinalamin®

INTERNATIONAL NON-PROPRIETARY NAME (INN): cattle retinal polypeptides

DOSAGE FORM AND STRUCTURE:
Lyophilisate for preparation of solution for intramuscular and parabulbar injections, 5 mg.
Each vial contains:
Active ingredient - Retinalamin 5 mg (complex of water-soluble cattle retinal polypeptide fractions);
Excipient - Glycine 17 mg (stabilizer).

PHARMACOLOGICAL CLASSIFICATION:
Nosological classification (ICD-10):
H35.3 Degeneration of macula and posterior pole
H35.5 Hereditary retinal dystrophy
H36.0 Diabetic retinopathy
H40.1 Primary open-angle glaucoma
H52.1 Myopia
S05 Injury of eye and orbit

ATC CODE: S01XA Other ophthalmologicals

PHARMACOLOGICAL ACTION: Ophthalmic, stimulator of tissue regeneration.

PHARMACODYNAMICS:
Retinalamin is a complex of water-soluble polypeptide fractions with the molecular weight of no more than 10,000 kDa. The agent has a stimulating effect on retinal photoreceptors and cellular elements; it improves functional interaction between pigment epithelium and outer segments of photoreceptors, it improves glial cells in patients with retinal dystrophy and accelerates the recovery of light sensitivity processes in retina. It normalizes vascular permeability, reduces local inflammation, and activates reparative processes in patients with diseases and traumas of the retina.

INTENDED USES:
Compensated primary open-angle glaucoma, diabetic retinopathy, post-traumatic and post-inflammatory central retinal dystrophy, myopia (within comprehensive treatment), central and peripheral tapetoretinal abiotrophy.

CONTRAINDICATIONS:
- Individual hypersensitivity to any of the medication components;
- Patients under 18 y.o. with compensated primary open-angle glaucoma, diabetic retinopathy, myopia (because of the lack of efficacy and safety data);
- Patients under 12 months with post-traumatic and post-inflammatory central retinal dystrophy, central and peripheral tapetoretinal abiotrophy;
- Pregnancy.

DOSAGE AND ADMINISTRATION:
Adults
With diabetic retinopathy, post-traumatic and post-inflammatory central retinal dystrophy, central and peripheral tapetoretinal abiotrophy:

parabulbar or intramuscular injections of 5-10 mg once a day. Treatment duration is 5–10 days; if necessary, it is repeated after 3–6 months.
With compensated primary open-angle glaucoma: parabulbar or intramuscular injections of 5 mg once a day. Treatment duration is 10 days; if necessary, it is repeated after 3–6 months.
With myopia: parabulbar injections of 5 mg once a day. Treatment duration is 10 days. It is recommended in combination with angioprotective agents and B vitamins.
The drug is dissolved in 1-2 ml of water for injection, a 0.9% solution of sodium chloride or a 0.5% solution of procaine (novocaine), directing the needle to the wall of the vial to avoid foaming.
In children at the age of 1–5 years with post-traumatic and post-inflammatory central retinal dystrophy, central and peripheral tapetoretinal abiotrophy: parabulbar or intramuscular injections of 2.5 mg once a day.
In children at the age of 6–18 years with post-traumatic and post-inflammatory central retinal dystrophy, central and peripheral tapetoretinal abiotrophy: parabulbar or intramuscular injections of 2.5–5.0 mg once a day. Dissolve the drug in 1-2 ml of 0.9% solution of sodium chloride, directing the needle toward the side of the vial to avoid foaming. Treatment duration is 10 days; if necessary, it is repeated after 3–6 months.

PRECAUTION:

Retinalamin® should be used in strict accordance with the doctor's prescription.
The vial with the solution cannot be stored and used after storage. A solution of Retinalamin® is not recommended to be mixed with other solutions.
When using a 0.5% solution of procaine (novocaine) as a solvent for Retinalamin®, the information on the contraindications, precautions and age restrictions indicated in the procaine (novocaine) description should be followed.
In case of missing an injection, it is not recommended to administer a double dose, the next injection should be carried out as usual on the intended day.

SIDE EFFECTS:

When used as indicated in the prescription, adverse effects are not reported. Allergic reactions are possible in case of individual intolerance to any component of the medication.

OVERDOSE:

No cases of the drug overdose have been reported.

INTERACTION WITH OTHER DRUGS:

The drug interaction of Retinalamin® is not described.

PREGNANCY AND LACTATION:

The drug is contraindicated during pregnancy. The drug may be used during lactation if prescribed by the doctor.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:

Caution should be taken when driving vehicles and operating machinery. Parabulbar injections of the drug and concomitant vision examinations may cause temporary visual impairments which may affect the performance of potentially hazardous activities that require special attention and quick reactions (driving, working with moving mechanisms).

STORAGE CONDITIONS:

Store in a dark, dry place, at 2–20 °C (35.6-68 °F). Keep out of the reach of children.
Shelf life: 3 years.
MANUFACTURER: GEROPHARM LTD, Russia. www.geropharm.com