

PACKAGE LEAFLET FOR USE

Gentaculin 0.3% eye ointment for dogs and cats

Gentamicin

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER, IF DIFFERENT

Balkanpharma-Razgrad AD

68 “Aprilsko vastanie” Blvd.

Razgrad 7200, Republic of Bulgaria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gentaculin 0.3% eye ointment for dogs and cats

Gentamicin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 g of the eye ointment contains 3 mg of gentamicin (as sulphate) and excipients: methyl parahydroxybenzoate, propyl parahydroxybenzoate, wool fat (lanolin) anhydrous, purified water and paraffin, white soft.

4. INDICATIONS

For use in dogs and cats, for the topical treatment of conjunctivitis, blepharitis, blepharoconjunctivitis, keratitis, hordeolum, dacryocystitis, crawling corneal ulcers, secondary infections of corneal erosions and ulcers, including corneal herpes; prophylactically, after extraction of foreign bodies from the cornea and conjunctiva; preoperatively and postoperatively, in extra- and intrabulbar operations.

5. CONTRAINDICATIONS

Hypersensitivity to aminoglycoside antibiotics.

6. ADVERSE REACTIONS

Transient redness of the ocular mucous membranes and allergy may be observed. With prolonged use, superinfection conditions (overgrowth of non-susceptible microorganisms – fungi, etc.) are likely to occur. In such cases, the administration should be discontinued and appropriate treatment should be instituted. Therefore, the treatment with Gentaculin 0.3% eye ointment is limited to not more than 7-10 days. If you notice any serious effects or other effects resulting from the use of this veterinary medicinal product, not mentioned in this package leaflet, please inform immediately your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

To be supplied only on veterinary prescription.

A column of the ointment with length of about 10 mm is squeezed in the lower conjunctival sac, 2-3 times daily. The treatment lasts 4 to 10 days.

For external use in the lower conjunctival sac.

9. ADVICE ON CORRECT ADMINISTRATION

The cone of the tube should not touch the eye.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 25 °C.

Do not freeze.

Keep the tube tightly closed.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton.

Shelf-life: 3 years.

Shelf-life after first opening the tube: 30 days at a temperature below 25° C.

12. SPECIAL WARNING(S)

None.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of empty packaging, unused or expired product in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2011

15. OTHER INFORMATION

Aluminum tubes with a tip, closed with a plastic screw cap, containing 5 g.