PACKAGE LEAFLET FOR USE

Tobraculin 0.3% eye drops, solution for dogs and cats

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

Tobraculin 0.3% eye drops, solution for dogs and cats

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

1 ml of the solution contains 3 mg of tobramycin (as sulphate).
Excipients: benzalkonium chloride, potassium dihydrogen phosphate, disodium phosphate dodecahydrate, sodium chloride, hydroxyethylcellulose, water for injections.

4. INDICATIONS

For the topical treatment of superficial external bacterial infections of the eye and its adnexa, caused by tobramycin-susceptible pathogenic microorganisms – conjunctivitis, blepharitis, blepharoconjunctivitis, keratitis, keratoconjunctivitis, hordeolum, dacrocystitis, crawling corneal ulcers; secondary infections of corneal erosions and ulcers; prophylactically, after extraction of foreign bodies from the cornea and conjunctiva; preoperatively and postoperatively, in extra- and intrabulbar operations.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients. Do not use other eye drops during the treatment with Tobraculin. Do not use in viral and fungal infections of the eyes.

6. ADVERSE REACTIONS

Serious adverse effects from the use of Tobraculin 0.3% eye drops have not been observed. Burning, itching and swelling of the eyelids, photophobia or conjunctival erythema are likely to occur. In such cases, the administration of the product should be discontinued.

With prolonged use of the product, disbacteriosis with overgrowth of microorganisms, non-susceptible to tobramycin, including fungi, is likely to occur. In such cases, appropriate treatment should be instituted.

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

Method of administration:

For external use through instilling into the lower conjunctival sac, taking care to avoid the contact betwen the dropper applicator and the eye and the skin of the hands. After each instillation, the inner corner of the eye is pressed for about 30-60 seconds, in order to prevent a leakage of the solution through the lacrimal ducts.

Dosage:

In mild to moderate inflammation, 1-2 drops are instilled every 4 hours. In acute infections, 2 drops are instilled every hour to improvement of the status, and after then, the regime can be switched to 1-2 drops every 4 hours. The treatment lasts 5 to 10 days.

9. ADVICE ON CORRECT ADMINISTRATION

The dropper applicator is sterile and therefore, when handling the product, it should not touch any surface, including the eyes of the animals and the hands of the person administering the product to the animals.

10. WITHDRAWAL PERIOD

Not required.

11. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.

Store in a dry place. Protect from direct sunlight.

Do not freeze.

Shelf-life after first opening the vial: 28 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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2012

15. OTHER INFORMATION

White plastic vials containing 5 ml, fitted with a dropper applicator and closed with a screw cap with a tamper-evident ring.