

PACKAGE LEAFLET FOR USE

Tobraculin-D eye drops, suspension 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-D eye drops, suspension for dogs and cats

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

1 ml of the suspension contains 3 mg of tobramycin (as sulphate) and 1 mg of dexamethasone.

Excipients: benzalkonium chloride, disodium edetate, potassium dihydrogen phosphate, disodium phosphate dodecahydrate, sodium chloride, polysorbate 80, hydroxyethylcellulose, water for injections.

4. INDICATIONS

The product is used in inflammatory conditions of the conjunctiva, cornea and anterior chamber of the eye, where the use of corticosteroids is recommended and there is a risk of or an existing superficial bacterial infection – conjunctivitis, keratitis, keratoconjunctivitis, blepharitis, blepharoconjunctivitis, hordeolum, dacrocystitis, iritis, after extraction of foreign bodies from the cornea and conjunctiva; preoperatively and postoperatively, in extra- and intrabulbar operations in dogs and cats.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Serious adverse effects from the use of Tobraculin-D 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. Delayed healing of ocular defects and an increase of the intraocular pressure may be observed.

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:

Shake the vial vigorously before use. Apply by instilling into the lower conjunctival sac, taking care to avoid the contact between 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 suspension through the lacrimal ducts.

Dosage:

Usually, 1-2 drops are instilled every 4-6 hours. In acute inflammation, the treatment can be initiated with 1-2 drops every 2 hours for the first 24-48 hours, and gradually, along with improvement of the clinical symptoms, be switched to a regime of 1-2 drops every 4-6 hours. The treatment lasts 5 to 10 days.

9. ADVICE ON CORRECT ADMINISTRATION

When handling the product, care should be taken for contamination of the skin of the hands, due to the risk of sensitisation.

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.