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Dechra Veterinary Products

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Isathal® 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits

Species: Rabbits, Cats, Dogs

Therapeutic indication:Pharmaceuticals: Antimicrobials: Topical preparations: Ear/eye/nose

Active ingredient: Fusidic Acid

Product: Isathal® 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits

Product index: Isathal 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits

Withdrawal notes: Not for use in rabbits intended for human consumption

Incorporating:

Qualitative and quantitative composition

1 g suspension contains: Active substance: Fusidic acid 10 mg

Excipients: Benzalkonium chloride 0.11 mg as antimicrobial preservative. Disodium edetate 0.5 mg as co-preservative.

Pharmaceutical form

Eye drops, suspension. A sterile, white to off-white, viscous formulation.

Clinical particulars

Target species

Dog, cat and rabbit.

Indications for use

Dog: For the topical treatment of conjunctivitis associated with *Staphylococcus aureus* and in particular the biotype *Staphylococcus intermedius*.

Cat: For the topical treatment of conjunctivitis associated with secondary staphylococcal infections.

Rabbit: For the topical treatment of conjunctivitis associated with staphylococcal infections.

Contraindications

The veterinary medicinal product should not be used in conjunctivitis cases associated with *Pseudomonas* spp.

Do not use in cases of known hypersensitivity to the active substance or any of the excipients.

Special warnings for each target species

In cats, the possibility of a primary cause of the conjunctivitis should be investigated and treated if possible.

In rabbits, conjunctivitis may be associated with dacryocystitis and/or dental disease. In such cases, appropriate additional treatment should be instituted.

Special precautions for use

When using the veterinary medicinal product, official and national antimicrobial policies should be taken into account. It is recommended that the use of the veterinary medicinal product should be based on bacteriological and susceptibility testing. If this is not possible, treatment should be based on epidemiological information on the susceptibility of the bacteria concerned. Using the veterinary medicinal product other than as indicated in this datasheet may increase the number of bacteria resistant to fusidic acid.

Special precautions for use in animals

For external use only.

When the tube is squeezed, the veterinary medicinal product comes out as a thick (viscous) drop. The drop quickly becomes liquid on contact with tear fluid and does not affect the sight.

Care should be taken to avoid contamination of the contents during use and to avoid the nozzle coming into direct contact with the eye. Avoid fingers touching the tube nozzle.

Do not use the same tube to treat different animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after applying the product.

Adverse reactions

Allergic reactions or hypersensitivity to the active substance or the excipients might occur. Discontinue use if hypersensitivity to the product develops.

Use during pregnancy and lactation

The product may be used safely in pregnant and lactating animals.

Amounts to be administered and administration route

One drop of the veterinary medicinal product should be instilled into the eye once or twice daily. Treatment should be continued for at least 24 hours after the eye has returned to normal.

If a clinical response is not evident after 5 days following the commencement of administration, the diagnosis should be re-established.

If the animal has one infected eye, it may be advisable to treat both eyes to prevent cross-infection. In such cases, it is better to treat the uninfected eye first to avoid transferring infection via the tube nozzle.

Withdrawal periods

Not for use in rabbits intended for human comsumption.

Pharmacological particulars

Pharmacotherapeutic group: Ophthalmologicals containing antibiotics.

ATCvet code: QS01AA13

Pharmacodynamic properties

Fusidic acid, the active substance of the veterinary medicinal product, is active against *Staphylococcus aureus* and in particular against the biotype *Staphylococcus intermedius* which is a common isolate from clinical cases of canine conjunctivitis.

In the cat, ocular bacterial infection is usually secondary to viral, Chlamydia or Mycoplasmal infection or trauma. Among the variety of bacteria found, the *Staphylococcus* spp. are considered to be sensitive to fusidic acid.

In the rabbit, ocular infections are associated with a variety of organisms which are sensitive to fusidic acid, the most common of which are *Staphylococci*.

Pharmacokinetic properties

The sustained release formulation of the veterinary medicinal product ensures prolonged retention within the conjunctival sac. Once or twice daily applications will provide inhibitory levels of fusidic acid against the sensitive organisms.

Studies have shown that fusidic acid penetrates well into the cornea and anterior chamber in humans and rabbits.

Pharmaceutical particulars

Excipients

Benzalkonium chloride

Disodium edetate

Mannitol

Carbomer

Sodium hydroxide

Water for injections

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the tube: 1 month.

Special precautions for storage

Do not store above 25˚C.

Replace the cap between applications.

Following withdrawal of first dose, use the product within 1 month.

Immediate packaging

Sterilised aluminium tube laminated on both sides of tube wall with high density polyethylene, with a high density polyethylene nozzle closed with a high density polyethylene screw cap.

Pack sizes: Available in a carton containing a 3 g and 5 g tube. Not all pack sizes may be marketed.

Disposal

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

Marketing Authorisation Holder (if different from distributor)

Dechra Veterinary Products A/S, Mekuvej 9, DK-7171 Uldum, Denmark.

Marketing Authorisation Number

Vm 24883/4003

Significant changes

Date of the first authorisation or date of renewal

11 November 1993

Date of revision of the text

April 2022

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description: Isathal 10 mg/g Eye Drops, Suspension for Dogs, Cats and Rabbits:

GTIN:05701170445596