1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isathal 10 mg/g eye drops, suspension for dogs, cats and rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of suspension contains:

Active substances:
Fusidic acid 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride (as antimicrobial preservative)	0.11 mg
Disodium edetate (as co-preservative)	0.5 mg
Mannitol	
Carbomer 974	
Sodium hydroxide	
Water for injections	

Sterile, white to off-white, viscous eye drops suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and rabbits.

3.2 Indications for use for each target species

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

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

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

3.3 Contraindications

Do not use in conjunctivitis associated with *Pseudomonas* spp.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.

Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. Using the veterinary medicinal product other than as indicated in the SPC may increase the number of bacteria resistant to fusidic acid.

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 veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs, cats, rabbits:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Allergic reaction[a], Hypersensitivity reaction[a]

[a] Discontinue use if hypersensitivity to the product develops.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Ocular use.
External use only.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not applicable.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not for use in rabbits intended for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS01AA13

4.2 Pharmacodynamics

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 frequently isolated from clinical cases of canine conjunctivitis.

In cats, ocular bacterial infections are usually secondary to viral, chlamydial or mycoplasmal infections or to trauma. Among the variety of bacteria found, *Staphylococcus* spp. are considered to be sensitive to fusidic acid.

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

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 1 month.

5.3 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.

5.4 Nature and composition of 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.

Cardboard box containing either a 3 g or a 5 g tube.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Veterinary Products A/S

7. MARKETING AUTHORISATION NUMBER(S)

VPA10803/004/001

8. DATE OF FIRST AUTHORISATION

15/11/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).