Summary of Product Characteristics

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 substance:			
Fusidic acid	10	mg	
Excipients:			
Benzalkonium chloride	0.11	mg	as antimicrobial preservative
disodium edetate	0.5	mg	as co-preservative

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, suspension.

A sterile, white to off-white, viscous formulation.

4 CLINICAL PARTICULARS

4.1 Target Species

Dog, cat and rabbit.

4.2 Indications for use, specifying the target species

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

For the topical treatment of conjunctivitis in the cat associated with secondary staphylococcal infections.

For the topical treatment of conjunctivitis in the rabbit associated with staphylococcal infections.

4.3 Contraindications

The veterinary medicinal product should not be used in conjunctivitis associated with *Pseudomonas* spp.
Do not use in cases of known hypersensitivity to the active ingredient.

4.4 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 dacrocystitis and/or dental disease. In such cases, appropriate additional treatment should be instituted.

4.5 Special precautions for use

Special precaution(s) 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 medicinal product to animals
Wash hands after applying the product.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions or hypersensitivity to the active substance or the excipients might occur.

Discontinue use if hypersensitivity to the product develops.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Not for use in rabbits intended for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Ophthalmologicals containing antibiotics

ATC Vet Code: QS01AA13

5.1 Pharmacodynamic properties

Fusidic acid, the active ingredient of the veterinary medicinal product, is active against *Staphylococcus aureus* and in particular against biotype *Staphylococcus intermedius* which is frequently isolated from clinical cases of canine conjunctivitis.

In the cat, ocular bacterial infection is usually secondary to viral, chlamydial or mycoplasmal infection or trauma. A greater variety of organisms are found. Among these *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 fucidic acid, the most common of which are *Staphylococci*.

5.2 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 fucidic acid against the sensitive organisms.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Mannitol
Carbomer 974
Sodium hydroxide
Water for injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25^{o}C.
Replace the cap between applications.
Following withdrawal of first dose, use the product within 1 month.

6.5 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.

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10803/004/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th November 2006

10 DATE OF REVISION OF THE TEXT

June 2014