*[Version 8.1,01/2017]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isathal 10 mg/g eye drops, suspension for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g eye drop suspension contains:

**Active substance:**
Fusidic acid 10.0 mg
(equivalent to fusidic acid hemihydrate 10.17 mg)

**Excipients:**
Benzalkonium chloride 0.11 mg
Disodium edetate 0.50 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dog.

### 4.2 Indications for use, specifying the target species

For the treatment of uncomplicated eye infection in dogs caused by fusidic acid sensitive gram positive bacteria.

### 4.3 Contraindications

The veterinary medicinal product should not be used in eye cases associated with *Pseudomanas* spp.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

Special precautions for use in animals

Care should be taken to avoid contamination of the contents during use and to avoid the nozzle coming into direct contact with the eye.
Do not use the same tube to treat different animals.
Use of the product should be based on identification and susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local/regional epidemiological information about susceptibility of the target bacteria.

"Use of the product should be in accordance with official, national and regional antimicrobial policies."

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

Wash hands after applying the product.

People with known hypersensitivity to fusidic acid should avoid contact with the veterinary medicinal product.

### 4.6 Adverse reactions (frequency and seriousness)

Allergy or hypersensitivity to the active substance or to any of the excipients may occur.

### 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

### 4.8 Interaction with other medicinal products and other forms of interaction

No data available.

### 4.9 Amounts to be administered and administration route

Ocular use.
One drop of the veterinary medicinal product should be instilled into the affected eye (the conjunctival sac of the lower eyelid) twice daily. Treatment should be continued for at least 5 days and at least 24 hours after the eye has returned to normal.
If a clinical response is not evident after 5 days following 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

None known.

### 4.11 Withdrawal period(s)

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ophthalmologicals, antibiotics.
ATC vet code: QS 01 AA 13.

### 5.1 Pharmacodynamic properties

Fusidic acid exerts its antibacterial properties by interfering with bacterial protein synthesis. Fusidic acid exhibits good activity against *Staph. intermedius, Staph. aureus* and *Staph. epidermidis,* regardless of the level of beta-lactamase production, and is particularly active against the biotype *Staphylococcus intermedius,* which is seen clinically in canine conjunctivitis. *Pseudomonas* and *Enterobacteriacae* are resistant.

| **Pathogenic bacteria** | **Fusidic acid** | **Fusidic acid** |
|---|---|---|

| | **Sensitive / Resistant** | **MIC** |
|---|---|---|
| Gram-positive bacteria<br>- *Staphylococcus pseudintermedius*<br>- *Streptococcus* spp.<br>- *Corynebacteria* spp. | <br>Sensitive<br>Sensitive<br>Sensitive | <br>$MIC_{90}$≅ 0.25-4 µg/ml<br>$MIC_{90}$≅ 8-16 µg/ml<br>$MIC_{90}$ ≅ 0.04 – 12.5 µg/ml |
| Gram-negative bacteria<br>- *Pseudomonas* spp.<br>- *E.coli* | <br>Resistant<br>Resistant | <br>>128 µg/ml<br>>128 µg/ml |

Data based on studies conducted mainly in Europe but also in North America between 2002 and 2011.

Two major mechanisms of resistance to fusidic acid have been reported in *S. aureus* – the alteration of the drug target site which is due to chromosomal mutations in FusA (encoding elongation factor EF-G) or FusE encoding ribosome protein L6, and the protection of the drug target site by FusB family proteins, including fusB, fusC, and fusD. The fusB determinant originally was found on a plasmid in *S. aureus* but has also been found on a transposon-like element or in a staphylococcal pathogenicity island.
No cross-resistance between fusidic acid and other antibiotics that are in clinical use has been identified.

### 5.2 Pharmacokinetic particulars

Fusidic acid shows good penetration in the cornea and the anterior chamber of the eye. The sustained release formulation of the veterinary medicinal product maintains active concentrations of fusidic acid in the tear fluids for over 12 hours after administration. The level of fusidic acid in the tear fluid of dogs 24 hours after the administration of 1 drop of the veterinary medicinal product is 1-15 mcg-ml (4.5 mcg/ml on average). Two treatments per day will ensure an effective concentration against sensitive organisms.

The calculated half-life for fusidic acid when administered to dogs in the form of this depot formulation is approximately 7.5 hours.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

### 6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

### 6.3 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

### 6.4. Special precautions for storage

Do not store above 25 °C.

### 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 and 5 g tube.
Not all pack sizes may be marketed.

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

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

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

## 10 DATE OF REVISION OF THE TEXT

## PROHIBITION OF SALE, SUPPLY AND/OR USE

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON 3 g/5 g**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isathal 10 mg/g eye drops, suspension for dogs
Fusidic acid

## 2. STATEMENT OF ACTIVE SUBSTANCES

1 g suspension contains:

Active substance:
Fusidic acid 10 mg

## 3. PHARMACEUTICAL FORM

Eye drops, suspension.

## 4. PACKAGE SIZE

3 g/5 g

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

Read the package leaflet before use.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ocular use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP: {month/year}
Once opened use within 1 month.

Once opened, use by: ___/___/___

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Tube 3 g/5 g**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isathal 10 mg/g eye drops, suspension for dogs

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Fusidic acid 10 mg/g

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 g/5 g

## 4. ROUTE(S) OF ADMINISTRATION

Ocular use.

## 5. WITHDRAWAL PERIOD(S)

Not applicable.

## 6. BATCH NUMBER

Lot: {number}

## 7. EXPIRY DATE

EXP: {month/year}
Once opened use within 1 month.

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**
Isathal 10 mg/g eye drops, suspension for dogs

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Veterinary Products A/S
Mekuvej 9
7171 Uldum
Denmark

Manufacturer responsible for batch release:
LEO Laboratories Ltd
285 Cashel Road
Dublin 12
Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isathal 10 mg/g eye drops, suspension for dogs
Fusidic acid

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

Each g eye drops suspension contains:

**Active substance:**
Fusidic acid 10.0 mg
(equivalent to fusidic acid hemihydrate 10.17 mg)

**Excipients:**
Benzalkoniumchloride 0.11 mg,
Disodium edetate 0.5 mg

Sterile, white to off white viscous eye drops suspension.

## 4. INDICATION(S)

For the treatment of uncomplicated eye infection in dogs caused by fusidic-acid sensitive gram positive bacteria.

## 5. CONTRAINDICATIONS

The veterinary medicinal product should not be used in conjunctivitis cases associated with *Pseudomanas* spp.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

## 6. ADVERSE REACTIONS

Allergy or hypersensitivity to the active substance or to any of the excipients may occur.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Ocular use.
One drop of the veterinary medicinal product should be instilled into the affected eye (the conjunctival sac/inner side of the lower eyelid) twice daily. Treatment should be continued for at least 5 days and 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.

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 10. WITHDRAWAL PERIOD(S)

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP.
The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 1 month.

## 12. SPECIAL WARNING(S)

Special precautions for use in animals:
Care should be taken to avoid contamination of the contents during use and to avoid the nozzle coming into direct contact with the eye.
Do not use the same tube to treat different animals.
Use of the product should be based on identification and susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local/regional epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after applying the product.
People with known hypersensitivity to fusidic acid should avoid contact with the veterinary medicinal product.

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

Overdose:
None known.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

## 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

## 15. OTHER INFORMATION

Tubes of 3 g or 5 g.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.