

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

{ Isathal 10 mg/g eye drops, suspension for dogs, cats and rabbits  
- CARTON 3 g / 5 g – common UK/IE }

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ISATHAL 10 mg/g eye drops, suspension for dogs, cats and rabbits  
Fusidic acid

**2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

1 g suspension contains:

Active substance:

Fusidic acid 10 mg

Excipients:

Benzalkonium chloride 0.11 mg as an antimicrobial preservative.

Disodium edetate 0.5 mg as a co-preservative.

**3. PHARMACEUTICAL FORM**

[Eye drops , suspension]

**4. PACKAGE SIZE**

3 g / 5 g

**5. TARGET SPECIES**

[For dogs, cats and rabbits]

**6. INDICATION(S)**

Read the package leaflet before use.

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

For ocular use.

For external use only.

[Read the package leaflet before use.]

**8. WITHDRAWAL PERIOD**

Withdrawal period: Not for use in rabbits intended for human consumption.

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

Wash hands after applying the product.

[Read the package leaflet before use.]

#### 10. EXPIRY DATE

EXP: {month/year}

Sterile - Shelf life after first opening the tube: 1 month.

Once opened, use by: \_\_\_/\_\_\_/\_\_\_

#### 11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Replace the cap between applications.

Keep the container in the outer carton.

#### 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.

UK: Vm 24883/4003

POM-V

IE: VPA 10803/004/001

POM

#### 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  
7171 Uldum  
Denmark

#### 16. MARKETING AUTHORISATION NUMBER(S)

Vm 24883/4003 - [stated in the box together with POM-V]

**17. MANUFACTURER'S BATCH NUMBER**

Lot: {number}

**ADDITIONAL INFORMATION**

[Pictogram dog, cat, rabbit]

[EAN code]

[GTIN code number]

[2D matrix including LOT, EXP end and GTIN details as requested by IFAH]

[Dechra logo]

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

{Isathal 10 mg/g eye drops, suspension for dogs, cats and rabbits –  
TUBE 3 g / 5 g – Common UK/IE}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

ISATHAL 10 mg/g eye drops, suspension for dogs, cats and rabbits  
Fusidic acid

**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**

For ocular use.  
For external use only.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIOD**

Withdrawal period: Not for use in rabbits intended for human consumption.

**6. BATCH NUMBER**

Lot: {number}

**7. EXPIRY DATE**

EXP: {month/year}  
Sterile - Shelf life after first opening the tube: 1 month.

**8. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**ADDITIONAL INFORMATION**

To be supplied only on veterinary prescription.

UK: Vm 24883/4003

POM-V

IE: VPA 10803/004/001

POM

Dechra Veterinary Products A/S

[Dechra logo]

[Pictogram of dog, cat and rabbit]

## **B. PACKAGE LEAFLET**

**PACKAGE LEAFLET FOR:  
ISATHAL 10 mg/g eye drops, suspension for dogs, cats and rabbits**

**This leaflet gives you some helpful information about Isathal. If you have any questions or are not sure about anything, ask your veterinary surgeon.**

**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 the batch release:**

LEO Laboratories Limited  
Dublin 12, Ireland

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT:**

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

**3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS:**

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 a co-preservative, mannitol, carbomer, sodium hydroxide and water for injections.

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

**4. INDICATION:**

Isathal eye drops are used for the topical treatment of conjunctivitis associated with an infection of your dog's, cat's or rabbit's eye. Isathal contains a well known antibiotic which kills the bacteria causing this infection.

**5. CONTRAINDICATIONS:**

- The drops should not be used if your dog, cat or rabbit is allergic or hypersensitive to the ingredients.
- Use the drops as instructed by your veterinary surgeon, as Isathal should not be used in specific types of conjunctivitis (associated with *Pseudomonas* spp.).

**6. ADVERSE REACTIONS:**

- Allergic reactions or hypersensitivity to the active substance or the excipients might occur. Stop using the product if an allergy develops.

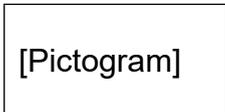
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## **7. TARGET SPECIES:**

Dogs, cats and rabbits.

## **8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION:**

- Isathal is used once or twice a day according to your veterinary surgeon's recommendations.
1. For ease of application, it is sometimes helpful if one person holds the animal and another person applies the drops. The animal should be held firmly in the sitting position. Small dogs, cats or rabbits should be placed on a table or similar surface.
  2. Remove discharge and debris from the corners and around the eye with a piece of cotton wool moistened with warm water or a ready-made eye lotion.
  3. Remove screw cap.
  4. Place one hand under the animal's chin and raise its head up slightly. Hold the head firmly. In the case of a dog, it may be necessary to apply a muzzle to prevent the dog injuring you. In the case of a cat or rabbit, if the animal is difficult to restrain, it might be helpful in order to keep the animal in the right position during the administration to wrap the body of the animal in a towel keeping its head clear off the towel (ask your veterinary surgeon for advice regarding this).
  5. Treat the uninfected eye first if advised to do so by your veterinary surgeon.
  6. Whilst holding the tube between the index finger and thumb of your other hand, place the side of this hand on the animal's head above the eye and use it to pull the upper eyelid upwards to expose the white of the eye – see illustration. Squeeze 1 drop of Isathal and allow it to fall onto the eyeball or underneath the upper eyelid making sure that the nozzle does not touch the eye or its surroundings. Then release the eyelid.
  7. In some rabbits, it may be easier to pull the lower eyelid down to apply the drop.
  8. Repeat this procedure with the infected eye.
  9. Replace the screw cap between applications; do not touch the nozzle with your fingers.
  10. If twice daily dosing is recommended, repeat this procedure the following morning or evening.
  11. Wash hands after applying the product.
  12. Complete the course as prescribed by your veterinary surgeon. The normal course is to continue treatment for at least 24 hours after the eye has returned to normal.



[Pictogram]

## **9. ADVICE ON CORRECT ADMINISTRATION:**

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 the SmPC may increase the number of bacteria resistant to fusidic acid.

### **Special precautions for use in animals**

- When the tube is squeezed, Isathal 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 of the tube coming into direct contact with the eye.
- You may find a white powder around the eye which is caused when the drops dry out. This is quite normal and is not harmful. It may be wiped off with moist cotton wool.
- If you forget to use the drops at the right time, use them as soon as you remember. Then go on as before.
- If there is no improvement after 5 days following the start of the course of treatment, please contact your vet.

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

- Wash hands thoroughly after applying the product.

### **10. WITHDRAWAL PERIOD:**

Not for use in rabbits intended for human consumption.

### **11. SPECIAL STORAGE PRECAUTIONS:**

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Replace the cap between applications.
- Do not use this veterinary medicinal product after the expiry date which is stated on the tube and carton after EXP. The expiry date refers to the last day of that month.
- Shelf life after first opening the tube: 1 month.
- After opening the tube for the first time add 1 month to calculate the date on which any product remaining in the tube should be discarded. This discard date should be written in the space provided on the carton.

### **12. SPECIAL WARNINGS:**

- For animal treatment only.
- For external use only.
- To be used under veterinary supervision.
- Do not use the same tube to treat different animals.
- Once the course of treatment is finished, do not use Isathal again except on the advice of your veterinary surgeon.

### **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS:**

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:**

April 2022

**15. ADDITIONAL INFORMATION**

Pack sizes: Available in 3 g and 5 g tubes.  
Not all pack sizes may be marketed.  
Veterinary medicinal product authorised for use in UK and Ireland.  
To be supplied only on veterinary prescription.

UK: Vm 24883/4003

POM-V

Prescription Only Medicine - Veterinarian

IE: VPA 10803/004/001

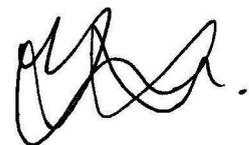
POM

Prescription Only Medicine

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

UK:

Dechra Veterinary Products Limited  
Sansaw Business Park  
Hadnall  
Shrewsbury  
Shropshire  
SY4 4AS  
United Kingdom



Approved: 12 April 2022