

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

### **Carton**

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

Optimmune 2 mg/g Eye Ointment

#### **2. STATEMENT OF ACTIVE SUBSTANCES**

Ciclosporin 2 mg/g

#### **3. PHARMACEUTICAL FORM**

Eye Ointment.

#### **4. PACKAGE SIZE**

3.5 g

#### **5. TARGET SPECIES**

**Target Species:** Dog.

#### **6. INDICATION(S)**

Not applicable.

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

**Route:** For external topical use only.

For topical administration to the conjunctival sac.

**Read package leaflet before use.**

## 8. WITHDRAWAL PERIOD

Not applicable.

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

**Read package leaflet before use.**

Avoid contact with the skin and eyes.

Wash hands after use.

Wear gloves when applying the ointment.

Squeeze the tube from the bottom and do not fold.

Care should be taken to avoid contamination of the contents during use.

Replace cap between applications.

## 10. EXPIRY DATE

EXP:

Once opened, use by:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Do not freeze.

Keep tube in outer carton.

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

For indications, contraindications, warnings, dosage and disposal advice: **Read package leaflet before use.**

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** [*Distribution category*]

For animal treatment only.

POM-V

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**

**MA holder in UK**

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

**MA Holder in Ireland and Distributor in Northern Ireland**

Intervet Ireland Ltd.

Magna Drive, Magna Business Park, Citywest Rd.

Dublin 24, Ireland

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

**UK only**

Vm 01708/4589

**IE only**

VPA 10996/242/001

**17. MANUFACTURER'S BATCH NUMBER**

Batch No:

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

**Tube**

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

Optimmune 2 mg/g Eye Ointment

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

Ciclosporin 2 mg/g

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

3.5 g

**4. ROUTE(S) OF ADMINISTRATION**

For external use only.

For topical administration to the conjunctival sac.

Read package leaflet before use.

**5. WITHDRAWAL PERIOD**

Not applicable.

**6. BATCH NUMBER**

Batch no. and expiry date: see end of tube.

**7. EXPIRY DATE**

Batch no. and expiry date: see end of tube.

Keep tube in outer carton. Once opened use within 1 month.

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

For animal treatment only.

To be supplied only on veterinary prescription.

### **UK:**

Vm 01708/4589

POM-V

### **IE:**

VPA 10996/242/001

POM

**PACKAGE LEAFLET FOR:**  
**Optimmune 2mg/g Eye Ointment**

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

Marketing authorisation holder:

**UK only:**

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

**IE only:** Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

Manufacturer for the batch release:

TriRx Segré, La Grindolière, Zone Artisanale, Segré, 49500 Segré-en-Anjou Bleu, France

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

Optimmune 2mg/g Eye Ointment

Ciclosporin

**3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

Each gram of eye ointment contains: 2mg Ciclosporin.

Translucent, colourless to light yellow ointment.

#### **4. INDICATION(S)**

For the treatment of chronic, recurrent conjunctivitis resulting from autoimmune disease of the eye. Optimmune is indicated for the therapeutic treatment of keratoconjunctivitis sicca (KCS, 'dry eye') and chronic superficial keratitis ('pannus').

Optimmune may be used to augment topical corticosteroids or as a substitute for corticosteroids when these are contraindicated by corneal ulceration.

#### **5. CONTRAINDICATIONS**

Do not use where fungal or viral infection of the eye is suspected.

#### **6. ADVERSE REACTIONS**

Slight eye irritation (e.g. eyeredness, blepharospasm, conjunctivitis) has been reported in rare cases in the first days of treatment. If the irritation persists beyond 7 days, treatment should be discontinued.

Inflammation and swelling of the skin of the eye lids have been observed in very rare cases.

In very rare cases, pruritus, skin lesions and hair loss have been reported in the area around the eyes; this may be associated with overflow of excess ointment.

Systemic reactions such as increased salivation, lethargy, inappetence and vomiting have been observed in very rare cases for which no confirmed conclusions concerning the causal relationship are available.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

## **7. TARGET SPECIES**

Dog.

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

For external topical use only.

For topical administration to the conjunctival sac.

Apply a small amount of ointment (approximately  $\frac{1}{4}$  inch or  $\frac{1}{2}$  cm) into the affected eye(s) every 12 hours.

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

Any excessive discharge in the eye should be removed prior to application of the ointment by gently cleansing or flushing the eye with a suitable non-irritating solution.

## **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 freeze.

Care should be taken to avoid contamination of the contents during use.

Replace cap between applications.

Keep tube in outer carton.

Shelf-life after first opening the container: 1 month.

Any contents remaining one month after the date on which the container was first opened should be discarded. When the container is opened for the first time, the

date on which any product remaining in the container should be discarded should be calculated. This discard date should be written on the space provided on the carton.

## **12. SPECIAL WARNING(S)**

Clinical experience has shown that 90% of dogs affected with KCS will require life-long therapy. However, if therapy is maintained, the prognosis is good providing that regular clinical assessment is conducted.

Similarly, chronic superficial keratitis may require continuous therapy although, as the condition is exacerbated by ultraviolet light, requirement for treatment may be suspended or reduced at certain times of the year.

In the treatment of KCS, it is important that continuous treatment is maintained. Studies have shown that stimulation of tear production ceases within 24 hours of withdrawing treatment. Increase in tear production is expected within 10 days but may not be maximal until 6 weeks from commencement of treatment.

For external topical use only. Care should be taken to avoid contamination of the contents during use.

Replace cap between applications.

### *User warnings:*

This product may cause skin and eye irritation. Avoid contact with the skin and eyes.

Wear gloves when applying the ointment.

Do not eat, drink or smoke while handling the product.

Wash hands and contacted skin thoroughly with soap and water immediately after use of the product.

In case of contact with the eyes, immediately rinse thoroughly with water.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Squeeze the tube from the bottom and do not fold.

### *Use during pregnancy and lactation:*

Do not administer to pregnant bitches. Studies to demonstrate safety in pregnant bitches have not been conducted.

*Overdose:*

Inflammation and swelling of the skin of the lids has been reported in a very few cases. This seems to be associated with overflow of excess ointment. Reduction of the quantity of ointment has resulted in resolution.

**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 products should be disposed in accordance with local requirements.

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

June 2021

**15. OTHER INFORMATION**

For animal treatment only.

Pack size: 3.5 g tubes.

Ciclosporin is an immunomodulator with lacrimomimetic and antiinflammatory activities. It is a highly lipophilic drug and is absorbed into the cornea in high concentrations. Ciclosporin also penetrates the lacrimal gland following administration. Ciclosporin exerts its immunosuppressive and anti-inflammatory effects by inhibiting the production of cytokines which up-regulate T-helper cell activity. This restores the function of lacrimal acinar epithelium under autoimmune attack and reduces infiltration of ocular tissues by inflammatory cells. In addition to its immunosuppressive activity, ciclosporin exerts a direct lacrimomimetic effect by blocking the inhibition of tear production by prolactin. Optimmune thus increases the flow of tears identical to natural tear secretions. As well as lubrication and wetting, epithelial growth factors and other components of tears are necessary for maintenance of corneal health.

Distributor in Northern Ireland:

Intervet Ireland Ltd.,

Magna Drive,

Magna Business Park,

Citywest Road,  
Dublin 24,  
Ireland

### **UK only**

Vm 01708/4589

POM-V

To be supplied only on veterinary prescription.

### **IE only**

VPA 10996/242/001

POM

Prescription Only Medicine.

### **Information for dog owners:**

Tears, and the tear film which covers the surface of the eye, are of vital importance and help to keep the eye healthy.

As well as providing lubrication, natural tears contain substances which prevent infection and are important in the protection and nutrition of the delicate cornea.

Some disorders reduce the production of tears, and the eye becomes dry, damaged and inflamed.

Without treatment, the condition of the eye deteriorates and may eventually lead to blindness. One of the most common of these 'dry eye' disorders is keratoconjunctivitis sicca or KCS. This and similar conditions can be caused by a disorder of the dog's own immune system, and will therefore continue to affect it throughout its life. Your veterinary surgeon has prescribed Optimune for your dog to help it produce tears and reduce the chronic inflammation which causes damaged and sore eyes.

Unlike treatment with artificial tears or lubricants, Optimune treats the underlying cause so that a normal film of tears is produced, even when the tear glands are diseased.

Optimmune should be administered twice each day, or as recommended by your veterinary surgeon. An increase in tear production is expected within 10 days, but it may take up to 6 weeks, for the full effect to be achieved.

In a few dogs, after perhaps months of treatment, the condition may appear to change making it necessary to alter the dose or give other medication in addition to Optimmune. If this happens to your dog, it is important that you consult your veterinary surgeon.

Points to remember:

- Continue treatment.

It is important that treatment is continued even when the condition of the eye has improved. If treatment is stopped completely, damage to the eye may occur before the signs of redness and inflammation re-appear.

- Don't run out of ointment.

In order to maintain and continue improvement, make sure that you have sufficient ointment available, and tell your vet in good time before you run out. Do not assume that when you finish one tube that the course of treatment has ended.

Using Optimmune:

Apply a small amount of Optimmune ointment (approximately  $\frac{1}{4}$  inch or  $\frac{1}{2}$  cm) into each affected eye every 12 hours, or as directed by your veterinary surgeon.

Gently pull down the lower eyelid, and squeeze the strip of ointment from the tube onto the inside of the eyelid. Squeeze the tube from the bottom and do not fold.

Optimmune has a special ointment base which helps to spread the treatment over the eye as the dog blinks.

Wear gloves when applying the ointment, and avoid getting the ointment on your skin or in your eyes. Always wash your hands, and any skin that has been in contact with the ointment, thoroughly with soap and water immediately after treating your dog.

If you get ointment in your eyes, immediately rinse thoroughly with water.

Do not eat, drink or smoke while handling the product. In case of accidental ingestion of the ointment, seek medical advice immediately and show this package leaflet or product packaging to your doctor.

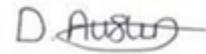
The tube may contain some air when first used; this is normal and results from the manufacturing process. The amount of ointment is carefully measured by weight ensuring the correct quantity in each tube of Optimune.

Storing Optimune:

Keep the product out of the sight and reach of children.

Optimune should not be stored above 25 °C, which means keeping it at normal room temperature. If the ointment appears too soft at room temperature, it may be stored in the refrigerator, but do not freeze.

Approved: 09/06/21

A handwritten signature in blue ink that reads "D. Austin". The signature is written in a cursive style with a horizontal line extending from the end.