PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optimmune 2 mg/g eye ointment

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains: Ciclosporin 2.0 mg

3. PACKAGE SIZE

3.5 g

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Ocular use.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
During administration, squeeze the tube carefully from the bottom and do not roll or fold the tube.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 1 month.
Once opened use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.
Avoid contamination of the contents during use.
Replace cap between applications.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/4134

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

3.5 g tube label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optimmune

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each g contains:
Ciclosporin 2.0 mg

3. BATCH NUMBER

Lot: see end of tube.

4. EXPIRY DATE

Exp.: see end of tube {mm/yyyy}
On the printed packaging, Lot and Exp information will be combined into a single statement as:
Lot and Exp.: see end of tube.

Once opened use within 1 month.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Optimmune 2 mg/g eye ointment for dogs

2. Composition

Each g contains:

Active substance:
Ciclosporin 2.0 mg

A translucent, colourless to light yellow ointment with no grittiness.

3. Target species

Dogs.

4. Indications for use

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

Special warnings:
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.

Special precautions for safe use in the target species:
For external topical use only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The veterinary medicinal product may cause skin and eye irritation. Avoid contact with the skin and eyes. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

Do not eat, drink or smoke while handling the veterinary medicinal product.
Wash hands and contacted skin thoroughly with soap and water immediately after use of the veterinary medicinal 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.

Pregnancy:
Do not use during pregnancy.
The safety of the veterinary medicinal product has not been established during pregnancy.

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 administered has resulted in resolution.

7. Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Eye irritation[1] (e.g. eye redness[1], blepharospasm[1] (eyelid twitching) [1], conjunctivitis[1]).
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Eyelid inflammation, swollen eyelid. Application site pruritus (itching)[2] application site lesion[2], application site hair loss[2]. Lethargy[3], inappetence[3]. Increased salivation[3], vomiting[3].

[1] Slight eye irritation has been reported in the first days of treatment. If the irritation persists beyond 7 days, treatment should be discontinued.

[2] In the area around the eyes. This might be associated with overflow of excess ointment.
[3] No confirmed conclusions concerning the causal relationship are available.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Ocular use.
For topical administration to the conjunctival sac.
Apply a small amount of ointment (approximately ¼ inch or ½ cm) into the affected eye(s) every 12 hours.
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.
Avoid contamination of the contents during use.

9. Advice on correct administration

Handle the tube with care.
When opening the tube for the first time, while breaking the seal on the cap, carefully grip the neck of the tube to avoid exerting a twisting force on the tube and damaging it.
On first opening, a small amount of ointment may be released from the nozzle.
During administration, squeeze the tube carefully from the bottom and do not roll or fold the tube.
Replace cap between applications.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not freeze.

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 precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/4134

Pack size:
Cardboard box with 1 x 3.5 g tube.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
TriRx Segré
La Grindolière
Zone Artisanale
Segré
49500 Segré-en-Anjou Bleu
France

Local representative:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
MK7 7AJ, United Kingdom

Contact details to report suspected adverse events:
UK (GB)
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

UK (NI)
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

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

17. Other information

Ciclosporin is an immunomodulator with lacrimomimetic and anti-inflammatory 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. The veterinary medicinal product 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.

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 this veterinary medicinal product 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, this veterinary medicinal product treats the underlying cause so that a normal film of tears is produced, even when the tear glands are diseased.

The veterinary medicinal product 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 this veterinary medicinal product. 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 the veterinary medicinal product:
Gently pull down the lower eyelid, and squeeze the strip of ointment from the tube onto the inside of the eyelid. The veterinary medicinal product has a special ointment base which helps to spread the treatment over the eye as the dog blinks.
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 the veterinary medicinal product.

Storing Optimmune:
The veterinary medicinal product should be kept at normal room temperature. If the ointment appears too soft at room temperature, it may be stored in the refrigerator.

POM-V Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 25 March 2026