SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Optimmune 2 mg/g eye ointment for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Ciclosporin 2.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Petrolatum lanolin alcohol
Maize oil, refined
Paraffin white soft

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

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

3.4 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.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10 000 animals treated):	Eye irritation[1] (e.g. eye redness[1], blepharospasm[1],conjunctivitis[1]).
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Eyelid inflammation, swollen eyelid. Application site pruritus[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy.

Pregnancy:
Do not use during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QS01XA18

4.2 Pharmacodynamics

The veterinary medicinal product is a pharmaceutically stable sterile ointment containing 0.2% Ciclosporin. Administration of the ointment improves chronic diseases of the cornea and conjunctiva resulting from autoimmune disease such as keratoconjunctivitis sicca (KCS, dry eye), chronic superificial keratitis (pannus), and plasmacytic infiltration of the nictitans ('plasmoma') in dogs. To be applied topically to each affected eye.

Ciclosporin is an immunomodulator nonpolar cyclic oligopeptide with lacrimomimetic and anti-inflammatory activities. It is produced by the fungus species *Tolypocladium inflatum gans*. 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. Studies have demonstrated that long term use of the veterinary medicinal product does not increase susceptibility of the eye to microbial infection.
Studies have shown that the cornea acts as a depot for ciclosporin, and that in ophthalmic use there is low systemic bioavailability.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 1 month.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Epoxy-phenol lacquered aluminium tube with a high density polyethylene nozzle closed with a tamper-evident high density polyethylene cap, screw fit.

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

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4134

8. DATE OF FIRST AUTHORISATION

9 June 1994

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 25 March 2026