

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Optimmune 2 mg/g Eye Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Ciclosporin 2mg/g

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Ointment. A translucent, colourless to light yellow ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Dog.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

For external topical use only.

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

Replace cap between applications.

Any contents remaining one month after the date on which the container was first opened should be discarded.

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

Avoid contact with skin.

Wear gloves when applying the ointment. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In rare cases slight eye irritation (e.g. eye redness, blepharospasm, conjunctivitis) has been reported 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 eyelids have been observed in very rare cases.

Furthermore, cases of pruritus, skin lesions, and hair loss in the area around the eyes have been reported in very rare cases. This might be associated with overflow of excess ointment.

In very rare cases systemic reactions such as increased salivation, lethargy, inappetence and vomiting have been observed 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)

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant bitches.

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ophthalmologicals ATCvet Code: QS01XA90

5.1 Pharmacodynamic properties

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.

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. Studies have demonstrated that long term use of Optimmune 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Petrolatum lanolin alcohol

Maize Oil

White Soft paraffin

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

Shelf-life after first opening the immediate packaging: 1 month.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

1.Pack size:

3.5 g tube in a cardboard carton and cardboard box containing 10 tubes packed as above

2.Container:

Epoxy-phenol lacquered aluminium tube with high density polyethylene nozzle

3.Closure: Tamper-evident high density polyethylene cap, screw fit.

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park, Citywest Road
Dublin 24
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/242/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th April 2007

10 DATE OF REVISION OF THE TEXT

June 2017