SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Demyrin 2 mg/g eye ointment
For DK, FI, IS, NO, SE: Demyrin vet. 2 mg/g eye ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of ointment contains:

Active substance:
Ciclosporin 2.0 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye ointment.
White to slightly yellow homogenous ointment.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

For the treatment of Keratoconjunctivitis sicca (KCS, 'dry eye').
For the treatment of chronic superficial keratitis ('pannus').

4.3 Contraindications

Do not use in cases of hypersensitivity to ciclosporin or any of the excipients.
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.
To achieve the best results in the treatment of keratoconjunctivitis sicca, ciclosporin should be given early in the disease before irreversible damage and fibrosis of the lacrimal tissue occurs.

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

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. Avoid application onto the eye lids or the surrounding area of the eyes.

Special precautions to be taken by the person administering the veterinary medicinal product to animals. Avoid contact with the skin and particularly any transfer of product from hands to your mouth or eyes. If any contact with fingers occurs, wash hands immediately.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Mild irritation in the first few days of therapy may occur. If such irritation persists over 7 days, treatment should be discontinued.
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.

4.7 Use during pregnancy, lactation or lay

Use is not recommended during pregnancy and lactation because the safety of the veterinary medicinal product has not been established during these times.Use only according to the benefit/risk assessment by the responsible veterinarian.

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. 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. Apply a small amount of ointment, approximately 0.5 cm to 1 cm (For UK only: ¼ to ½ inch) into the affected eye(s) every 12 hours.
The duration of treatment depends on the severity of the condition and the response to treatment.

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 PROPERTIES

Pharmacotherapeutic group: Opthalmologicals, other opthalmologicals, ciclosporin
ATCvet code: QS01XA18

5.1 Pharmacodynamic properties

Administration of the ointment improves chronic diseases of the cornea and conjunctiva resulting from autoimmune disease such as keratoconjunctivitis sicca (KCS, dry eye), chronic superficial keratitis (pannus).
Ciclosporin A is an immunomodulator nonpolar cyclic oligopeptide with lacrimominetic 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 A also penetrates the lacrimal gland following administration.

Ciclosporin A 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 A exerts a direct lacrimomimetic effect by blocking the inhibition of tear production by prolactin.

The 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 product does not increase susceptibility of the eye to microbial infection.

5.2 Pharmacokinetic particulars

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Petrolatum and lanolin alcohol

Maize oil, refined
Paraffin, white soft

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Aluminum tube lacquered with epoxy-phenol containing 3.5 g with a LDPE nozzle. The cap is a tamper-evident HDPE screw fit cap.

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

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

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
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8. MARKETING AUTHORISATION NUMBER

Vm 00879/4055

9. DATE OF FIRST AUTHORISATION

23 May 2017

10. DATE OF REVISION OF THE TEXT

May 2017

Approved: 23/05/2017