ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

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
ciclosporin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 g of ointment contains 2.0 mg ciclosporin

3. PHARMACEUTICAL FORM

Eye ointment

4. PACKAGE SIZE

3.5g

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Ocular use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use by…
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. 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

Elanco Europe Ltd.
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4055

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

5 g TUBE

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
ciclosporin (EN/Latin)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2.0 mg/g ciclosporin

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

3.5g

4. ROUTE(S) OF ADMINISTRATION

Ocular use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Demyrin 2 mg/g eye ointment
Demyrin vet. 2 mg/g eye ointment (DK, FI, IS, NO, SE)

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

Marketing authorisation holder:
Elanco Europe Ltd.
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL
United Kingdom

Manufacturer responsible for batch release:
Tubilux Pharma S.p.A., Ophthalmic Products and Sterile Manufacturing
Via Costarica 20/22 00040, Pomezia (RM),
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Demyrin 2 mg/g eye ointment
Demyrin vet. 2 mg/g eye ointment (DK, FI, IS, NO, SE)
ciclosporin

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

1 g of ointment contains 2.0 mg ciclosporin as active substance.
White to slightly yellow, homogeneous ointment.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to ciclosporin or any of the excipients.
Do not use where fungal or viral infection of the eye is suspected.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Dogs.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Before applying the ointment clean away any discharge or excess ointment from around the eye with a suitable non-irritating solution or water. Apply the eye ointment by gently lowering the lower eyelid and applying the product into the pocket now exposed between the eye and lower eyelid. Your dog will spread the treatment over the eye by blinking.
The duration of the treatment depends on the severity of the condition and how your dog responds to treatment.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Shelf life after first opening the container is 28 days.
For UK only: When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Clinical experience has shown that 90% of dogs affected with 'dry eyes' or KCS will require life-long therapy. However, if therapy is maintained, the prognosis is good providing that regular clinical assessment is conducted.
Similarly, 'pannus' or 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 'dry eyes' or 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.

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.
Replace cap between applications.

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.

Use during pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, 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 has resulted in resolution.

Incompatibilities:
None known.

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

15. OTHER INFORMATION

Demyrin is available in a 3.5 g fill tube.

Approved: 23/05/2017