ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment for dogs
Clindamycin

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:

Clindamycin (as clindamycin hydrochloride) 10 mg

3. PHARMACEUTICAL FORM

Ointment

4. PACKAGE SIZE

20 gram

5. TARGET SPECIES

Dog

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
This product may cause hypersensitivity reactions. Wear gloves when applying the product.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening: 28 days
Once opened, use by __/__

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 C.
Do not freeze.

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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4011

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ALUMINIUM TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment for dogs
clindamycin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each gram contains:

Clindamycin (as clindamycin hydrochloride) 10 mg

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

20 gram

4. ROUTE(S) OF ADMINISTRATION

For cutaneous use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Clindacutin 10 mg ointment for dogs

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

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16;
4941 SJ Raamsdonksveer
The Netherlands.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment for dogs
clindamycin

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

Each gram contains:

Active substance:
Clindamycin (as clindamycin hydrochloride) 10 mg

White to yellowish ointment for cutaneous use.

4. INDICATIONS

For the treatment of superficial infected wounds caused by bacteria susceptible to clindamycin (in particular *Staphylococcus* spp. and *Streptococcus* spp.).
For the treatment of superficial interdigital pyoderma caused by *Staphylococcus pseudintermedius*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, to lincomycin or to any of the excipients.

Clindamycin should not be used for hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion in those species could cause severe digestive disorders.

6. ADVERSE REACTIONS

Hypersensitivity reactions of the skin (e.g. pain, redness and itching) are possible. Antibiotic-associated diarrhoeas are possible.

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs

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

Carefully apply a thin layer of ointment to the area of the skin to be treated, 3 to 4 times daily to ensure the area to be treated is covered with ointment all day, until clinical resolution of all lesions.

The maximum duration of treatment for superficial, infected wounds is 7 days. For the treatment of
superficial interdigital pyoderma the maximum duration of treatment is 14 days.

9. ADVICE ON CORRECT ADMINISTRATION

For cutaneous use.

10. WITHDRAWAL PERIOD

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: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
Cross-resistance has been shown between lincosamides (including clindamycin), erythromycin and other macrolides. Use of clindamycin should be carefully considered when antimicrobial susceptibility testing has shown resistance to lincosamides, erythromycin and other macrolides because its effectiveness may be reduced.

Special precautions for use in animals:
Oral ingestion (including licking) of the product by treated animals should be avoided. This product may be irritating to the mucous membranes and eyes. Avoid contact with the mucous membranes and/or eyes.

Use of the product should be based on identification and susceptibility testing of the target pathogens. If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target bacteria at local/regional level.

Use of the product should be in accordance with official, national and regional antimicrobial policies.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to clindamycin and may decrease the effectiveness of treatment with lincosamides, erythromycin or other macrolides due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The active substance clindamycin, as well as the excipients polyethylene glycol and propylene glycol, may cause hypersensitivity (allergy) reactions. Skin contact with the veterinary medicinal product should be avoided. Wear gloves when applying the product. If contact occurs, wash hands or exposed skin and seek medical advice in case of hypersensitivity reactions.

This product may be irritating to the mucous membranes and/or eyes. Avoid contact with the mucous membranes and/or eyes including hand-to-eye contact. If contact occurs, rinse with clean water. If eye irritation persists, seek medical advice and show the package leaflet or label to the physician.

Pregnancy:
No teratogenic effects were found in studies with laboratory animals (rats and mice) after oral administration or in pregnant women during the second and third trimester after systemic administration of the active substance clindamycin. However, no data is available for gestating bitches.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Lactation:
No data is available on safety in lactating bitches.Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Antagonism occurs with β-lactam antibiotics, chloramphenicol and macrolides.

Overdose (symptoms, emergency procedures, antidotes):
When applied cutaneously, at a multiple of the recommended therapeutic dose, no direct side effects related to the use of clindamycin in dogs were observed.
After oral ingestion, due to grooming or licking, side effects such as vomiting and diarrhoea may occur, as these adverse events have been described after oral clindamycin treatment.
Overdosing the amount of ointment, may increase the risk of oral ingestion.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Aluminium tube of 20 g in a cardboard box. The tube is sealed with a tamper evident aluminium membrane and closed with a white high-density polyethylene screw cap.

Approved 03 March 2021