PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
Clindamycin (as clindamycin hydrochloride) 10 mg

3. PACKAGE SIZE

20 gram

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once opened, use by __/__

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

This product may cause hypersensitivity reactions. Wear gloves when applying the product.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/4011

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - ALUMINIUM TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment

2. STATEMENT OF ACTIVE SUBSTANCES

Each gram contains:
Clindamycin (as clindamycin hydrochloride) 10 mg

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Cutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Clindacutin 10 mg/g ointment for dogs

2. Composition

Each gram contains:

Active substance:
Clindamycin (as clindamycin hydrochloride) 10 mg

White to yellowish ointment.

3. Target species

Dogs.

4. Indications for use

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. Special warnings

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

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

Use of the veterinary medicinal 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 veterinary medicinal 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:
Laboratory studies in rats and mice have not produced any evidence of teratogenic effects after oral administration.
No teratogenic effects were found 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:
When applied cutaneous, 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.

7. Adverse events

Dog

Undetermined frequency (cannot be estimated from the available data)	Diarrhoea[a] Allergic skin reaction (e.g. pain, redness and itching)

[a] Antibiotic-associated

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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 periods

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/4011

Aluminium tube of 20 g in a cardboard box.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

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

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

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

17. Other information

POM-V

Gavin Hall

Approved: 23 January 2025