

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacutin 10 mg/g ointment for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:

Clindamycin (as clindamycin hydrochloride) 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Macrogol 4000
Cod Liver oil (type A)
Propylene glycol
Purified water

White to yellowish ointment.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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*.

3.3 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.

3.4 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.

3.5 Special precautions for use

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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dog

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

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

3.8 Interaction with other medicinal products and other forms of interaction

Antagonism occurs with β -lactam antibiotics, chloramphenicol and macrolides.

3.9 Administration routes and dosage

Cutaneous use.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QD06AX.

4.2 Pharmacodynamics

Mode of action

Clindamycin is a semi-synthetic antibiotic produced by 7(S)-chloro substitution of the 7(R)-hydroxy group of the natural antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

Clindamycin, a mainly time-dependent acting antibiotic, acts by a bacteriostatic mechanism where the drug interferes with protein synthesis within the bacterial cell, thus inhibiting the growth and multiplication of the bacteria.

Clindamycin binds to the 23S ribosomal RNA component of the 50S subunit. This prevents amino acids binding on these ribosomes, and therefore inhibits peptide bond formation. The ribosomal sites are close to those bound by macrolides, streptogramins or chloramphenicol.

Antibacterial spectrum

The spectrum of activity of lincosamides is similar to the macrolide antibiotics and includes *streptococcus* spp., *staphylococcus* spp. (including β -lactamase-forming *Staphylococcus aureus*).

MIC data

CLSI clindamycin veterinary breakpoints are available for dogs in *Staphylococcus* spp. and Streptococci- β -haemolytic group in skin and soft tissue infections: S \leq 0.5 μ g/ml; I=1-2 μ g/ml; R \geq 4 μ g/ml (CLSI February 2018). These breakpoints are established for systemic treatment and should be considered as indicative for topical treatment only.

Type and mechanism of resistance

Clindamycin belongs to the lincosamide group of antibiotics. Resistance can develop to the lincosamides alone, but more commonly cross-resistance occurs among macrolides, lincosamides and streptogramin B antibiotics (MLSB group). Resistance is the result of methylation of adenine residues in the 23S RNA of the 50S ribosomal subunit, which prevents drug binding to the target site. Different bacterial species are able to synthesize an enzyme, encoded by a series of structurally related erythromycin ribosomal methylase (erm) genes. In pathogenic bacteria, these determinants are mostly borne by plasmids and transposons that are self-transferable. The erm genes occur predominantly as variants erm(A) and erm(C) in *Staphylococcus aureus* and as variant erm(B) in *Staphylococcus pseudintermedius*, *streptococci* and *enterococci*.

MLSB inducible resistance is not detected by standard in vitro susceptibility testing methods. The CLSI recommends the D-zone test to be routinely performed in veterinary diagnostic laboratories in order to detect clinical isolates with inducible resistance phenotype. Clindamycin use should be discouraged in these patients.

The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in Europe. Studies (2010) report an incidence between 25 to 40%.

4.3 Pharmacokinetics

No data is available for clindamycin plasma levels or clindamycin levels in the inflamed area after application of the formulation.

All other information indicates that clindamycin is hardly absorbed through the skin.

In case clindamycin will be absorbed through the skin, distribution will be high due to the basic nature of the substance, and accumulation will occur in tissues with a lower pH than plasma.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.

Do not freeze.

5.4 Nature and composition of immediate packaging

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

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

Medicines should not be disposed of via wastewater or household waste.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

ALUMINIUM TUBE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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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

9. BATCH NUMBER

Lot {number}

B. 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:

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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.

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Pregnancy:

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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)
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^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: {national system details}.

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 or household waste.

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

Aluminium tube of 20 g in a cardboard box.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

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>:>

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

17. Other information