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

3 PHARMACEUTICAL FORM

Ointment.
White to yellowish ointment for cutaneous use.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the 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*.

4.3 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.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

For 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other antibiotics for topical use
ATC vet code: QD06AX

5.1 Pharmacodynamic properties

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 ß-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≤0.5µg/ml; I=1-2µg/ml; R≥4µg/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%.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 4000
Cod Liver oil (type A)
Propylene glycol
Purified water

6.2 Major incompatibilities

Not applicable.

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

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

6.5 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.

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/031/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 April 2021

10 DATE OF REVISION OF THE TEXT