1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 300 mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
300 mg of clindamycin as clindamycin hydrochloride.

Excipients:

Qualitative composition of excipients and other constituents
Ludipress (Lactose monohydrate, Povidone and Crospovidone)
Microcrystalline cellulose
Sodium laurilsulfate
Colloidal anhydrous silica
Magnesium stearate
Grilled meat flavour

A plain white to off white tablet with a cross break line on one side.
The tablets can be divided into halves or quarters.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of *Staphylococcus*, *Streptococcus*, *Bacteroides*, *Fusobacterium necrophorum* and *Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus*.

3.3 Contraindications

Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses, or ruminants because ingestion of clindamycin by these species may result in severe gastrointestinal disturbances.

Do not use in cases of known hypersensitivity to all lincosamides.

3.4 Special warnings

Cross-resistance has been shown between clindamycin and lincomycin in target pathogen(s), which is common also to erythromycin and other macrolide antibiotics.

Use of the clindamycin should be carefully considered when susceptibility testing has shown resistance to lincomycin, 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:

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed. Canines with severe renal and/or hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examination during clindamycin therapy.

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

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

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

An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after the administration of the product.
People with known hypersensitivity to lincosamides (lincomycin, clindamycin) should avoid contact with the veterinary medicinal product.
Do not eat, drink, or smoke while handling the product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency	Vomiting and Diarrhoea[1] Small intestinal bacterial overgrowth[2]

[1] Vomiting and diarrhoea are observed occasionally.
[2] Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as resistant Clostridia and yeasts. In cases of severe infection, appropriate measures should be taken according to the clinical situation.

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 and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only according to the benefit-risk assessment by the responsible veterinarian.
High dose laboratory studies in rats suggests that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females.

Fertility:
The safety of the veterinary medicinal product has not been established in breeding male dogs.

3.8 Interaction with other medicaments and other forms of interaction

Neuromuscular blocking effects have been observed with clindamycin possibly leading to an increase of efficacy of other neuromuscular blocking agents. The simultaneous use of such drugs must be handled with care.
Clindamycin should not be used simultaneously with chloramphenicol or macrolides because their action site is also the 50s subunit and antagonistic effects can possibly occur.
When clindamycin and aminoglycoside antibiotics (e.g., gentamicin) are used simultaneously adverse interactions (acute renal failure) cannot be fully excluded.

3.9 Administration route and dosage

For oral administration.
To ensure a correct dosage, body weight should be determined as accurately as possible.

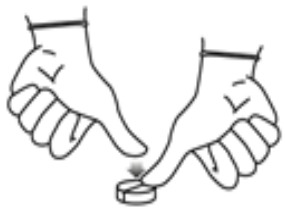
Infected wounds, abscesses, oral cavity/dental infections:
5.5 mg/kg clindamycin every 12 hours for 7 - 10 days (i.e., 1 tablet per 54 kg bodyweight twice daily). If no improvement is seen within 4 days, the sensitivity of the pathogens involved should be redetermined.

Dental and periodontal infections - In the case of dental/surgical treatment due to dental infection, treatment may be started before the dental/surgical treatment.

Osteomyelitis:
11 mg/kg clindamycin every 12 hours for at least 4 weeks (i.e., 2 tablets per 54 kg bodyweight twice daily). If no improvement is seen within 14 days, the sensitivity of the pathogens involved should be re-determined.

Tablets can be divided into halves or quarters to ensure accurate dosing.
To break a cross scored tablet into quarters, place the tablet on an even surface with the scored side up and apply pressure on the middle with your thumb.

To break a tablet into two halves, place the tablet on an even surface with the scored side up, hold one half of the tablet and press down on the other half.



Return any divided tablets to the blister pack or container and use within 72 hours. Divided tablets should be used at the next administration. Any divided tablets remaining after the last administration of the product should be discarded.

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

No adverse reactions have been observed in dogs after oral doses of 300 mg/kg.

Occasional vomiting, inappetence, diarrhoea, leukocytosis and increases in liver enzymes (AST, ALT) have been observed. In such cases, treatment should be stopped immediately, and the animals treated symptomatically.

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 Period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QJ01FF01

4.2 Pharmacodynamics

Clindamycin is primarily a bacteriostatic antibiotic of the lincosamide group, which acts by inhibition of protein synthesis. Clindamycin is a chlorinated analogue of lincomycin.
The antibiotic activity of clindamycin is based on the inhibition of bacterial synthesis. Reversible coupling to the 50s subunit of the bacterial ribosome inhibits *inter alia* the translation of tRNA-bound amino acids, thereby preventing elongation of the peptide chain. Because of this, the mode of action of clindamycin is predominantly bacteriostatic.

Clindamycin has been shown to have in-vitro activity against the following organisms:
Staphylococcus spp; *Streptococcus* spp; *Bacteroides* spp; *Fusobacterium* spp; *Clostridium* spp.

Clindamycin and lincomycin show cross-resistance, which is common also to erythromycin and other macrolide antibiotics. Acquired resistance can occur, by methylation of the ribosomal binding site via chromosomal mutation in gram positive organisms, or by plasmid-mediated mechanisms in gram negative organisms.

4.3 Pharmacokinetics

Clindamycin is almost completely absorbed after oral administration. Peak serum concentrations are attained approximately 1 hour after administration at a dose rate of 10 mg/kg. C_{max} 3.3 microgram/ml (non-fasting) - 5.0 microgram/ml (fasting).

Clindamycin penetrates well and may concentrate in some tissues.
The t ½ of clindamycin is approximately 4 hours.
Approximately 70% clindamycin is excreted in the faeces and approximately 30% in the urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale in HDPE containers: 5 years.
Shelf life of the veterinary medicinal product as packaged for sale in blisters: 2 years.
Return any divided tablets to the blister pack or container and use within 72 hours.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Divided tablets should be stored in the original pack. Keep the blister in the outer carton.

5.4 Nature and composition of immediate packaging

White high density polyethylene bottle with child resistant tamper evident polypropylene closure containing pack size: 6, 10, 14, 16, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100 and 200 tablets.

Blister (45um soft temper aluminium/ 30 um hard temper aluminium) pack sizes: 6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300, 500 and 1000 tablets.

Pack sizes for blisters:
Pack size: 6 tablets: A box of 3 blisters. Each blister contains 2 tablets.
Pack size: 10 tablets: A box of 5 blisters. Each blister contains 2 tablets.
Pack size: 14 tablets: A box of 7 blisters. Each blister contains 2 tablets.
Pack size: 20 tablets: A box of 10 blisters. Each blister contains 2 tablets.
Pack size: 28 tablets: A box of 14 blisters. Each blister contains 2 tablets.
Pack size: 30 tablets: A box of 15 blisters. Each blister contains 2 tablets.
Pack size: 42 tablets: A box of 21 blisters. Each blister contains 2 tablets.
Pack size: 50 tablets: A box of 25 blisters. Each blister contains 2 tablets.
Pack size: 56 tablets: A box of 28 blisters. Each blister contains 2 tablets.
Pack size: 60 tablets: A box of 30 blisters. Each blister contains 2 tablets.
Pack size: 70 tablets: A box of 35 blisters with each blister containing 2 tablets.
Pack size: 84 tablets: A box of 42 blisters. Each blister contains 2 tablets.

Pack size: 98 tablets: A box of 49 blisters. Each blister contains 2 tablets.
Pack size: 100 tablets: A box of 50 blisters. Each blister contains 2 tablets.
Pack size: 140 tablets: A box of 70 blisters with each blister containing 2 tablets.
Pack size: 180 tablets: A box of 90 blisters. Each blister contains 2 tablets.
Pack size: 200 tablets: A box of 100 blisters. Each blister contains 2 tablets.
Pack size: 250 tablets: A box of 125 blisters. Each blister contains 2 tablets.
Pack size: 280 tablets: A box of 140 blisters with each blister containing 2 tablets.
Pack size: 300 tablets: A box of 150 blisters. Each blister contains 2 tablets.
Pack size: 500 tablets: A box of 250 blisters. Each blister contains 2 tablets.
Pack size: 1000 tablets: A box of 500 blisters. Each blister contains 2 tablets.

Pack sizes for containers:
The container pack sizes and volumes are as follows:
300mg:

Pack size (tablets)	Container volume
6, 10	35ml
14, 16, 20	75ml
28, 30	100ml
42, 50, 56, 60	150ml
70, 84	250ml
98, 100	300ml
200	600ml

Not all pack sizes may be marketed.

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

Chanelle Pharmaceuticals Manufacturing Limited.

7. MARKETING AUTHORISATION NUMBER

VPA10987/144/005

8. DATE OF THE FIRST AUTHORISATION

01/06/2007

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

05/04/2024

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).