Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindacyl 300 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Clindamycin (as Clindamycin Hydrochloride) 300 mg
Excipients:
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the treatment of:
Infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-sensitive species of:

- *Staphylococcus* spp.
- *Streptococcus* spp.
- *Bacteroides* spp.
- *Fusobacterium necrophorum*
- *Clostridium perfringens*

Osteomyelitis

- *Staphylococcus aureus*

4.3 Contraindications

Do not use in cases of known hypersensitivity to lincosamides.
Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants because ingestion of clindamycin by these species may result in severe gastro-intestinal disturbance.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals
During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed. Patients with severe renal and/or hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examinations during clindamycin therapy.

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

Special precautions to be taken by the person administering the veterinary medicinal products to animals
Wash hands after the administration of the product. Persons with known hypersensitivity to lincosamides (lincomycin, clindamycin) should not handle the product. Do not eat, drink or smoke while handling the product.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea are observed occasionally. 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.

4.7 Use during pregnancy, lactation or lay

While high dose studies in rats suggests that clindamycin is not a teratogen and does not significantly affect the breeding performance of males and females, safety during pregnancy and lactation or in breeding male dogs has not been established. Therefore, the administration of the veterinary medicinal product during pregnancy and lactation should be the subject of a benefit/risk assessment by the veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

Neuromuscular blocking effects have been observed with clindamycin possibly leading to an increase of efficacy of other neuromuscular blocking agents. The simultaneous use of drugs must be handled with care. Clindamycin should not be used simultaneously with chloramphenicol or macrolids because of their action site is also the 50 s 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.

4.9 Amounts to be administered and administration route

For oral administration.
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 the dental/surgical treatment due to dental infection, treatment may be started before the dental/surgical treatment.

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.
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.
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 redetermined.
To ensure a correct dosage, bodyweight should be determined as accurately as possible.

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

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, lincosamides.
ATC Vet Code QJ01FF01

5.1 Pharmacodynamic properties

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 of the 50 s 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 macrolid-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.

5.2 Pharmacokinetic particulars

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 µg/ml (non-fasting) -5.0 µg/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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ludipress (composed of Lactose Monohydrate, Povidone & Crospovidone)
Microcrystalline Cellulose
Sodium Laurilsulfate
Silica, Colloidal Anhydrous
Magnesium Stearate
Grilled meat flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Return any divided tablets to the blister pack or containerand use within 72 hours.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 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

Pack sizes for containers:
pack sizes and volumes are as follows:

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

Not all pack sizes may be marketed.

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

Chanelle Pharmaceuticals Manufacturing Limited
Ida Industrial Estate
Dublin Road
Loughrea
Co. Galway
Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/161/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 July 2008
Date of last renewal: 29 July 2013

10 DATE OF REVISION OF THE TEXT

January 2022