SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 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 breakline 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

Clinacin 300 mg Tablets are indicated for the treatment of infected wounds, abscesses, superficial pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive staphylococci, streptococci, bacteroidaceae, *Fusobacterium necrophorum*, *Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus*. Clinacin 300 mg Tablets can also be used to help provide antimicrobial cover during dental procedures.

4.3 Contraindications

Do not administer to animals with hypersensitivity to clindamycin and lincomycin preparations.
Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants.

4.4 Special warnings for each target species

Before the use of Clinacin 300 mg tablets, the identification of causative pathogenic micro-organisms should be carried out and the sensitivity to clindamycin should be established. Clindamycin and lincomycin show parallel resistance. There is a partial cross-resistance to erythromycin and other macrolide antibiotics.

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 very severe hepatic disturbances accompanied by severe metabolic aberrations should be dosed with caution and should be monitored by serum examination during high dose clindamycin therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
None

4.6 Adverse reactions (frequency and seriousness)

Clindamycin sometimes causes the overgrowth of non sensitive organisms such as resistant clostridia and yeasts. In cases of superinfection, appropriate measures should be taken according to the clinical situation. Vomiting and diarrhoea are observed occasionally

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 in gestating bitches or 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 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 concomitant use of such drugs must be handled with care.
Clindamycin should not be used concomitantly with chloramphenicol or macrolides because they may antagonise each other at the site of action.

4.9 Amounts to be administered and administration route

For oral administration.
For treatment of infected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for 7 - 10 days (i.e. 1 tablet per 54 kg bodyweight twice daily). Treatment may be extended to a maximum of 28 days based on clinical judgement. If no improvement is seen within 4 days, the sensitivity of the pathogens involved should be re-determined.

For the treatment of superficial pyoderma administer 11 mg/kg every 24 hours (i.e. 2 tablets per 54 kg bodyweight once daily). Continue treatment for at least 21 days.
For the treatment of osteomyelitis administer 11 mg/kg every 12 hours (i.e. 2 tablets per 54 kg bodyweight twice daily) for at least 28 days. If no improvement is seen within 14 days, the sensitivity of the pathogens involved should be redetermined.
To help provide antimicrobial cover during dental procedures, a 10 day course of 5.5 mg/kg every 12 hours is recommended (i.e. 1 tablet per 54 kg twice a day beginning 5 days before the intended procedure and continuing for 5 days thereafter).

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.

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

Symptoms of overdose include vomiting, inappetency and diarrhoea.
In such cases, treatment should be stopped immediately and the dogs 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, a chlorinated analogue of lincomycin, is an antibiotic with bacteriostatic action. Bactericidal actions have also been reported.
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 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 rapidly absorbed; following oral administration up to 90% of the active ingredient is absorbed from the gastro-intestinal tract.

After a single administration of one tablet to fasting dogs maximum plasma levels (C_{max}) of 5 µg/ml are found compared to 3.4 µg/ml in non-fasting dogs. Bioavailability is greater in fasting dogs than fed dogs.
Clindamycin crosses the placental barrier and can be detected in milk

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ludipress (Lactose Monohydrate, Povidone & Crospovidone)
Microcrystalline Cellulose
Sodium Lauryl Sulphate
Colloidal silicon dioxide
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 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.

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

Clinacin 300 mg Tablets are presented in either white high density polyethylene bottle with child resistant tamper evident polypropylene closure, containing 6, 10, 14, 16, 20, 28, 30, 42, 50, 56, 60, 70, 80, 84, 98, 100 and 200 tablets or blister (45um soft temper aluminium/ 30um hard temper aluminium) containing 6, 10, 14, 20, 28, 30, 42, 50, 56, 60, 70, 84, 98, 100, 140, 180, 200, 250, 280, 300, 500 and 1000 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7. MARKETING AUTHORISATION HOLDER

Chanelle Animal Health Limited
7 Rodney Street
Liverpool
L1 9HZ
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

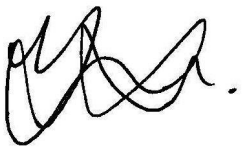
Vm 11990/4053

9. DATE OF THE FIRST AUTHORISATION

10 February 2010

10. DATE OF REVISION OF THE TEXT

September 2020



Approved: 30 September 2020