Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 150 mg Tablets for Dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance: Clindamycin 150 mg (as clindamycin hydrochloride)

Excipient:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
An oblong white tablet, with a break-line on one side.

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 clindamycin or lincomycin.

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.

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 examination during clindamycin therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after the administration of the product. Persons with known hypersensitivity to lincosamides (lincomycin, clindamycin) should not handle 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 super-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 Clinacin Tablets 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 such drugs must be handled with care. Clindamycin should not be used simultaneously with chloramphenicol or macrolids because 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 27 kg bodyweight twice daily). If no improvement is seen within 4 days the sensitivity of the pathogens involved should be re-determined

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 27 kg bodyweight twice daily). If no improvement is seen within 14 days the sensitivity of the pathogens involved should be re-determined.

Treatment with Clinacin should be based on susceptibility testing.

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

Doses of 300 mg/kg have been tolerated by dogs with no adverse reactions. 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

ATCvet code: QJ01FF01
Pharmacotherapeutic group: Lincosamides, antibacterials for systemic use.

5.1 Pharmacodynamic properties

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 almost completely absorbed after oral administration. Peak serum concentrations are attained approximately 1 hour after administration at a dose rate of 10mg/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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Povidone
Crospovidone
Microcrystalline Cellulose
Sodium Lauryl Sulphate
Colloidal Silicon Dioxide
Magnesium stearate.

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary product as packaged for sale: 5 years

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 10, 16, 20, 30, 50, 80 or 100 tablets.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/144/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th November 1999
Date of last renewal: 15th November 2006

10 DATE OF REVISION OF THE TEXT

November 2018