Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 25 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Clindamycin 25 mg
(as Clindamycin hydrochloride)

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet. A small round white tablet with a break-line on one side and the letter J embossed on both sides of the breakline. The tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and Cats.

4.2 Indications for use, specifying the target species

Clinacin 25 mg Tablets are antibiotics indicated for the treatment of infected wounds, abscesses, pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive staphylococci, streptococci, bacteroidaceae, *Fusobacteriumnecrophorum, Clostridium perfringens* and osteomyelitis caused by *Staphylococcus aureus.* Clinacin 25 mg Tablets can also be used to help provide antimicrobial cover during dental procedures.

4.3 Contraindications

Do not use in case of hypersensitivity to clindamycin or lincomycin.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
During prolonged osteomyelitis 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.
The product should not be used in cats for longer than 2 weeks as it may cause liver and gall bladder damage.

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)

Clindamycin and lincomycin show parallel-resistance. There is a partial cross-resistance to erythromycin and other macrolide-antibiotics.

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/queens or breeding male dogs/cats 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 concomitant use of such drugs must be handled with care.

Clindamycin should not be used concomitantly with chloramphenicol or macrolids because they antagonise each other at the site of action.

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, pyoderma, oral cavity/dental infections:
5.5 mg/kg clindamycin every 12 hours for 7 - 10 days (i.e. 1 tablet per 4.5 kg bodyweight twice daily). In dogs 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 redetermined.

Treatment for pyoderma in dogs should continue for at least 3 weeks.

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 4.5 kg twice a day beginning 5 days before the intended procedure and continue for 5 days thereafter).

Osteomyelitis:
For the treatment of osteomyelitis in dogs administer 11 mg/kg clindamycin every 12 hours for at least 4 weeks (i.e. 2 tablets per 4.5 kg bodyweight twice daily). If no improvement is seen within 14 days the sensitivity of the pathogens involved should be redetermined.
Treatment with Clinacin should be based on susceptibility testing.

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

Doses of five times the recommended dose have been tolerated by dogs and cats. Occasional vomiting, inappetency and diarrhoea 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 a chlorinated analogue of lincomycin. The antibiotic activity of clindamycin is based on the inhibition of bacterial protein 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 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

Microcrystalline cellulose
Sodium laurilsulfate
Colloidal anhydrous silica
Magnesium stearate
Ludipress (composed of lactose monohydrate, povidone and crospovidone)

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal 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

Polyethylene bottle with tamper evident snap-cap closures containing 50 and 100 tablets.
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
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10987/144/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 October 1999
Date of last renewal: 28 October 2009

10 DATE OF REVISION OF THE TEXT

April 2019