SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinacin 150mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance: Clindamycin, 150mg (as Clindamycin Hydrochloride)

Excipient(s): for a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablets.
An oblong white tablet with a breakline on one side.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

Clinacin 150 mg Tablets are indicated in dogs 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 150 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 use of Clinacin 150 mg tablets, the identification of causative pathogenic micro-organisms should be carried out and their susceptibility 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

i. 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.

ii. Special precautions for 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.

4.8 Interaction with other medicinal products 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
27 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 redetermined.

For the treatment of superficial pyoderma administer 11 mg/kg every 24 hours (i.e. 2 tablets per 27 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 27 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 27 kg twice a day beginning 5 days before the intended procedure and continuing for 5 days thereafter).

Minimum bodyweight to be treated with the 150 mg tablets is 13.5 kg.

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 PROPERTIES

Pharmacotherapeutic group: Antibiotic

ATC Vet Code: QJ01FF01

5.1 Pharmacodynamic properties

Clindamycin, a chlorinated analogue of lincomycin, is an antibiotic with bacteriostatic action. Bacterial actions have also been reported.

5.2 Pharmacokinetic properties

Clindamycin is rapidly absorbed; following oral administration up to 90% of the active ingredient is absorbed form the gastro-intestinal tract.
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 and Crospovidone),
Microcrystalline Cellulose,
Sodium lauryl sulphate,
Colloidal silicon dioxide,
Magnesium stearate.

6.2 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

Clinacin 150mg Tablets are presented in white High Density Polythylene (HDPE) bottle with child-resistant tamper evident snap-cap closures, containing 10, 16, 20, 30, 50, 80 and 100 tablets. Not all pack sizes may be marketed. The container is presented in a carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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 11990/4026

9. DATE OF FIRST AUTHORISATION

12 March 2002

10. DATE OF REVISION OF THE TEXT

March 2019

Approved: 22 March 2019

D Austin