SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 150 mg capsules for dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	mg per capsule
Clindamycin. (as clindamycin hydrochloride)	150.0
Excipients:	
Capsule body	
Azorubine (E122)	0.041
Indigo carmine FD&C Blue 2 (E132)	0.026
Capsule cap	
Azorubine (E122)	0.182
Indigo carmine FD&C Blue 2 (E132)	0.009
Titanium Dioxide (E171)	0.304
Ink:	
Iron oxide black (E172)	
Titanium dioxide (E171)	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard
Lavender body and maroon cap marked CL150 in white ink on the capsule cap.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use (specifying the target species)

The product is 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*. The product can also be used to help provide antimicrobial cover during dental procedures.

4.3 Contra-Indications

Do not administer to animals with hypersensitivity to clindamycin or to any of the excipients or to lincomycin preparations.
Do not administer to rabbits, guinea pigs, chinchillas, hamsters, 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

Before the use of the product, the identification of causative pathogenic micro-organisms should be carried out and the sensitivity to clindamycin should be established.

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.
Use of the product is not recommended in suckling puppies (see section 4.7)
Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.
Official and local antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to clindamycin and may decrease the effectiveness of treatment with lincomycin or macrolide antimicrobials due to the potential for cross resistance
Clindamycin and erythromycin show parallel resistance. Partial cross-resistance has been demonstrated between clindamycin, erythromycin and other macrolides antibiotics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In persons hypersensitive (allergic) to lincosamides (lincomycin, clindamycin), this product can, in serious cases, cause swelling of the face, lips and eyes, or breathing difficulties.
Those with known hypersensitivity to lincosamides should not handle the product.
Accidental ingestion of this product may cause transient gastrointestinal effects, and so should be avoided.
If you develop symptoms following exposure or in case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.

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. Clindamycin crosses the placental and blood-milk barriers. Treatment of lactating females can cause diarrhoea in puppies. Therefore the adminstration 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.
Clindamycin may reduce plasma levels of cyclosporin with a risk of lack of activity.
During the simultaneous use of clindamycin and aminoglycosides (eg gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded.

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

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 periods

Not applicable.

5. PHARMACOLOGICAL 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. 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

Lactose monohydrate
Maize starch
Magnesium stearate
Talc

Capsule body:
Azorubine (E122)
Indigo carmine FD&C blue 2 (E132)
Gelatin

Capsule cap:
Azorubine (E122)
Indigo carmine FD&C blue 2 (E132)
Titanium Dioxide (E171)
Gelatin

Ink
Iron oxide black (E172)
Titanium dioxide (E171)
Shellac
Propylene glycol
Sodium hydroxide
Povidone
Ammonium hydroxide 28%
Strong ammonia solution
Potassium hydroxide

6.2 Major Incompatibilities

Not applicable.

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

Blister strips composed of PVC/PE/PVdC film and sealed with Aluminium foil.
Capsules are presented as 2, 4, 6, 8 or 10 per strip.
Carton with blister strips of: 2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80 , 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 112, 120, 128, 130, 140, 150, 154, 160, 168, 180, 182, 186, 190, 196, 200, 210, 224, 240, 250, 252, 256, 260, 266, 270, 280, 290, 294, 300, 308, 320, 350, 390, 392, 448, 500, 450, 540, 546, 600, 602, 700, 750, 800, 798, 810, 896, 900 and 1000 Capsules

Not all pack sizes may be marketed.

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

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 Ltd.
7 Rodney Street
Liverpool, L1 9HZ

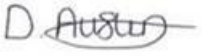
8. MARKETING AUTHORISATION NUMBER

Vm 11990/4057

9. DATE OF FIRST AUTHORISATION

16 July 2013

10. DATE OF REVISION OF THE TEXT

August 2018

Approved: 14 August 2018