Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 300 mg capsules for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Active substance:
Clindamycin (as Clindamycin Hydrochloride) 300 mg
Excipients:
For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Capsule
The capsule has a blue body and a blue cap.

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-susceptible species of *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp., *Clostridium perfringens* and *Fusobacterium necrophorum*.

For the treatment of osteomyelitis caused by Staphylococcus aureus.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients or to lincomycin or to pirlimycin. 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. Animals 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.

Inappropriate use of the product or deviating from the instructions given in 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.

Whenever possible, clindamycin should only be used based on susceptibility testing of bacteria isolated from the animal.
Official national and local antimicrobial policies should be taken into account when the product is used.
Clindamycin and erythromycin show parallel-resistance with lincomycin and co-resistance with other macrolide antibiotics. There is a partial cross-resistance to erythromycin and other macrolides.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to lincosamides (pirlimycin, lincomycin, clindamycin) should avoid contact with the veterinary medicinal product.
Wash hands after handling tablets.
Do not eat, drink or smoke while handling the product.
Accidental ingestion may result in gastro-intestinal effects such as abdominal pain and diarrhoea. Care should be taken to avoid accidental ingestion.
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)

Vomiting and diarrhoea are uncommonly observed. Clindamycin uncommonly 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 the veterinary medicinal product during pregnancy and lactation should be the subject of a benefit/risk assessment by the veterinarian. Clindamycin can pass the blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhea in puppies.

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 macrolide 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. Clindamycin may reduce the levels of cyclosporine, concomitant use should be avoided.

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 capsule per 54 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 capsules per 54 kg bodyweight twice daily). If no improvement is seen within 14 days the sensitivity of the pathogens involved should be re-determined.

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

In dogs, oral doses of clindamycin up to 300 mg/kg/day did not result in toxicity. 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

Pharmacotherapeutic group: Antibacterials for systemic use, lincosamides.
ATC Vet Code QJ01FF01.

5.1 Pharmacodynamic properties

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 and lincomycin show cross-resistance, which is common also to erythromycin and other macrolide-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.

Clindamycin has been shown to have in-vitro activity against the following organisms (see the following MICs):

- Aerobic Gram-positive cocci, including: *Staphylococcus aureus* and *Staphylococcus pseudintermedius (penicillinase and non-penicillinase producing strains), Streptococcus spp. (except Streptococcus faecalis).*

- Anaerobic Gram-negative bacilli, including: *Bacteroides* spp*., Fusobacterium necrophorum*.
- Clostridia: Most *Clostridium perfringens* are susceptible.

MIC data

CLSI clindamycin veterinary breakpoints are available for dogs in *Staphylococcus* spp. and Streptococci-ß-haemolytic group in skin and soft tissue infections: S ≤ 0.5 µg/ml;

I=1-2µg/ml; R ≥ 4 µg/ml. (CLSI July 2013).

The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in Europe. Recent studies (2010) report an incidence between 25 to 40%.

5.2 Pharmacokinetic particulars

Clindamycin is almost completely absorbed after oral administration. Clindamycin is approximately 93% bound to plasma proteins. Peak serum concentrations are attained approximately 1 hour after administration at a dose rate of 10 mg/kg, C_{max} 3.3 mg/ml (non-fasting) - 5.0 mg/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

Maize starch
Talc
Magnesium Stearate
Lactose Monohydrate

Capsule:
Blue body (Gelatine, Water, Patent blue V E131, Titanium dioxide E171).
Blue cap (Gelatine, Water, Patent blue V E131, Titanium dioxide E171).

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 4 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, 994 and 1000 capsules.
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 product or waste material derived from such veterinary medicinal product 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)

VPA10987/163/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 June 2013
Date of last renewal: 29 June 2018

10 DATE OF REVISION OF THE TEXT

November 2018