SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25 mg/ml oral solution for cats and dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active Substance:
Clindamycin 25 mg
(as Clindamycin Hydrochloride 27.15 mg)

Excipients:
Ethanol 96% 90.56 mg
For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Cats and dogs.

4.2 Indications for use (specifying the target species)

Cats:
For the treatment of infected wounds and abscesses caused by clindamycin-sensitive species of *Staphylococcus* spp. and *Streptococcus* spp.

Dogs:
- 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., *Clostridium perfringens, Fusobacterium necrophorum*.
- Adjunctive treatment of mechanical or surgical periodontal therapy in the treatment of infections of the gingival and periodontal tissues.
- For the treatment of osteomyelitis caused by *Staphylococcus aureus*.

4.3 Contra-Indications

Do not use in rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants because ingestion of clindamycin by these species may cause severe gastro-intestinal disorders, that can sometimes be fatal.
Do not use in cases of hypersensitivity to either clindamycin or lincomycin, or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Inappropriate use of the product may increase the prevalence of bacteria resistant to clindamycin. Whenever possible, clindamycin should only be used based on susceptibility testing.
Official national and local antimicrobial policies should be taken into account when the product is used.
Clindamycin shows parallel-resistance with lincomycin and co-resistance with erythromycin. There is a partial cross-resistance to erythromycin and other macrolides.
In case of administration of high doses of clindamycin or during prolonged therapy of one month or greater, tests for liver and renal functions and blood counts should be performed periodically.
In dogs and cats with kidney problems and/or liver problems, accompanied by severe metabolic aberrations, the dose to be administered should be carefully determined and their condition should be monitored by performing serum tests during treatment.
The use of the product is not recommended in neonates.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after administration.
Persons with known hypersensitivity to lincosamides (lincomycin and clindamycin) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Other precautions:
None.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, lethargy, vomiting and diarrhoea may be observed.
Clindamycin sometimes causes the overgrowth of non sensitive organisms such as resistant *clostridia* and yeasts. In case of secondary infection, the treatment should be stopped and appropriate measures should be taken based on clinicalobservations.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

very rare (less than 1 animal in 10,000 animals, 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, the safety of the veterinary medicinal product in gestating bitches/queens or breeding male dogs/cats has not been established.

Use only according to the benefit/risk assessment by the responsible veterinarian.

Clindamycin can pass the blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhea in puppies and kittens.

4.8 Interaction with other medicaments and other forms of interaction:

- Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicat complex may reduce lincosamides digestive absorption. These digestive topics should be administered at least 2 hours before clindamycin.
- Cyclosporin: clindamycin may reduce levels of this immunosuppressive drug with a risk of lack of activity.

- Neuro-muscular blocking agents: Clindamycin possesses intrinsic neuromuscular blocking activity and should be used cautiously with other neuromuscular blocking agents (curares). Clindamycin may increase neuromuscular blockade.

- Do not use clindamycin simultaneously with chloramphenicol or macrolides as they both target the ribosome 50S subunit and antagonist effects may develop.
- When using simultaneously clindamycin and aminoglycosides (i.e gentamicin), the risk of adverse interactions (acute renal failure) cannot be excluded.

4.9 Amounts to be administered and administration route

For oral administration only.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Recommended dosage:
Cats:

- Infected wounds, abscesses: 11 mg clindamycin per kg of body weight per 24h or 5.5 mg/kg per 12h for 7 to 10 days

The treatment should be stopped if no therapeutic effect is observed after 4 days.

Dogs:
- Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of body weight per 24h or 5.5 mg/kg per 12h for 7 to 10 days.

The treatment should be stopped if no therapeutic effect is observed after 4 days.
- Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight every 12 hours during a period of 28 days minimum. The treatment should be discontinued if no therapeutic effect is observed in the first 14 days.

Dosage	Volume to be administered per kg bodyweight
5.5 mg/kg	Corresponding approximately to 0.25 ml per kg
11 mg/kg	Corresponding approximately to 0.5 ml per kg

A 3 ml graduated syringe is provided to facilitate the administration of the veterinary medicinal product.

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

Doses of 300 mg/kg were tolerated by dogs without having adverse effects.
Vomiting, loss of appetite, diarrhoea, leukocytosis and elevations in liver enzymes (AST, ALT) were observed occasionally. In such cases, discontinue treatment immediately and establish a symptomatic treatment.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infectives for systemic use, lincosamides.
ATCvet-code: QJ01FF01.

5.1 Pharmacodynamic properties

Clindamycin is mainly a bacteriostatic antibiotic belonging to the group of lincosamides. Clindamycin is a chlorinated analogue of lincomycin. It works by inhibiting bacterial protein synthesis. The reversible coupling to the sub-unit 50-S bacterial ribosome inhibits translation of amino acids linked to the tRNA, thereby preventing elongation of the peptide chain. That is why the mode of action of clindamycin is predominantly bacteriostatic.
Clindamycin and lincomycin have cross-resistance, which is also common between erythromycin and other macrolides.

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 in vitro activity against the following micro-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. Maximum serum concentrations of 8 µg/ml (without influence of the bolus) were obtained 1 hour after a dose of 11 mg per kg.
Clindamycin is widely distributed and can concentrate in certain tissues.
The half-life of clindamycin is about 4 hours. Approximately 70% of clindamycin is excreted in faeces and about 30% in urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Sorbitol, liquid (non-crystallising) E420
Disodium Edetate
Propylene Glycol E1520
Sodium Saccharin E954
Citric Acid Monohydrate E330
Purified Water

6.2. Incompatibilities

Do not mix this product with any other veterinary medicinal products.

6.3. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year (PET bottle)
Shelf life of the veterinary medicinal product as packaged for sale: 3 years (Glass bottle)
Shelf life after first opening the immediate packaging: 28 days

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

Carton box containing clear polyethylene terephthalate (PET) bottle or Type III amber glass bottle of 22 ml with HDPE/LDPE or polypropylene tamper proof closure supplied with a low density polyethylene measuring syringe.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER:

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 08749/4032

9. DATE OF FIRST AUTHORISATION

31 May 2012

10 DATE OF REVISION OF THE TEXT

January 2017

Approved: 18 January 2017