

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clindaseptin 25mg/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 a 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*, *Fusobacterium necrophorum*, *Clostridium perfringens*
- 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 Contraindications

Do not use in rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants because ingestion of clindamycin by these species may cause severe gastrointestinal disorders.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after administration.

People 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)

Vomiting and diarrhoea are occasionally observed.

Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as resistant clostridia and yeasts. If superinfection occurs, the treatment should be stopped and appropriate measures should be taken based on the clinical situation.

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 accordingly 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 diarrhoea in puppies.

4.8 Interaction with other medicinal products and other forms of interaction

Neuromuscular blocking effects were observed with clindamycin, which may possibly enhance the activity of other neuromuscular blocking agents. The simultaneous use of such products must be made with caution.

Do not use clindamycin together with chloramphenicol or macrolides as they share the same binding site on the ribosomes.

During the simultaneous use of clindamycin and aminoglycosides (eg gentamicin), the risk of adverse interactions (acute renal failure) cannot be 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 only.

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 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 is active in vitro against many Gram-positive bacteria, Gram positive and Gram-negative anaerobic bacteria. Most aerobic or facultative Gram-negative bacteria are resistant to clindamycin.

CLSI clindamycin veterinary breakpoints are available for dogs in *Staphylococcus* spp. in skin and soft tissue infections: S $\leq 0.5\mu\text{g/ml}$; I=1-2 $\mu\text{g/ml}$; R $\geq 4\mu\text{g/ml}$ (CLSI January 2010).

5.2 Pharmacokinetic particulars

Clindamycin is almost completely absorbed after oral administration. Maximum serum concentrations of 8 $\mu\text{g/ml}$ (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

Sorbitol, liquid (non-crystallising)

Ethanol 96 %

Disodium Edetate

Propylene Glycol

Sodium Saccharin

Citric Acid Monohydrate

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: 2 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 product or waste materials derived from the use of such products

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 Pharmaceutical Manufacturing Limited
Loughrea, Co. Galway
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 08749/4032

IE: VPA 10987/097/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31 May 2012

10 DATE OF REVISION OF THE TEXT

December 2012

To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility.