SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 25 mg/ml oral solution for cats and dogs
Zodon, 25 mg/ml oral solution for cats and dogs (EE, LT, LV)
Zodon vet 25 mg/ml oral solution for cats and dogs (BE, LU, NL)
Givix vet (DK, FI, NO, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Clindamycin .....25 mg
(equivalent to 27,15 mg clindamycin hydrochloride)

Excipients:
Ethanol 96% (E1510)..... 72 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution
Clear, amber 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-susceptible 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 hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion 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 including the D-zone test.
Official national and local antimicrobial policies should be taken into account when the product is used.
Clindamycin is likely to favour the proliferation of non-susceptible organisms such as resistant *Clostridia spp* and yeasts. In case of secondary infection, appropriate corrective measures should be taken based on clinical observations.
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 appropriate blood 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 carefully after use.

People with known hypersensitivity to lincosamides (clindamycin and lincomycin) should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental ingestion as this may result in gastro-intestinal effects such as abdominal pain and diarrhoea.
In case of accidental ingestion, particularly by a child, or allergic reaction seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Vomiting and/or diarrhoea have been reported very rarely

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, the safety of the veterinary medicinal product in pregnant 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 placenta and blood-milk barrier. As a consequence, treatment of lactating females can cause diarrhoea in puppies and kittens.

4.8 Interaction with other medicinal products and other forms of interaction

- Aluminium salts and hydroxides, kaolin and Aluminium-Magnesium-Silicate complex may reduce the gastrointestinal absorption of lincosamides. Products containing these substances 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 clindamycin and aminoglycosides (e.g. gentamicin) simultaneously, the risk of adverse interactions (acute renal failure) cannot be excluded.

4.9 Amounts to be administered and administration route

For oral administration only
Recommended dose:

Cats:
Infected wounds, abscesses: 11mg of 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 for 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

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

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

The solution is flavoured. The solution can be administered directly into the mouth of the animal or added to a small quantity of food.

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

No adverse effects have been reported in dogs after administration of high dosage up to 300 mg/kg clindamycin.
Vomiting, loss of appetite, diarrhoea, leukocytosis and elevated liver enzymes have been observed occasionally. In such cases, discontinue the treatment and administer 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 Gram-negative bacteria are resistant to clindamycin.
"CLSI clindamycin veterinary breakpoints are available for dogs in Staphylococcus spp. and Streptococci-ß-haemolytic group in skin and soft tissue infections: S ≤0.5µg/ml; I=1-2µg/ml; R ≥ 4µg/ml". (CLSI July 2013).
The incidence of resistance to lincosamides in *Staphylococcus spp*. appears to be wide-ranging in Europe. Literature data (2016) report an incidence between 25 to 40%.

5.2 Pharmacokinetic particulars

Clindamycin is almost completely absorbed after oral administration. After oral administration of 11mg/kg, maximum plasma concentrations of 8µg/ml are reached within one hour (without any influence of food).
Clindamycin is widely distributed and may concentrate in some tissues.
Elimination half life of clindamycin is around 4 hours. Approximately 70% is excreted in faeces and 30% in the urine.
Clindamycin is approximately 93% bound to plasma proteins.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96% (E1510)
Glycerol
Sorbitol liquid (non crystallising)
Sucrose
Propylene glycol
"Grilled note" flavour
Citric acid monohydrate
Purified water

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 30°C

6.5 Nature and composition of immediate packaging

A cardboard box containing:

- a 20 mL amber translucent multidose bottle made in glass material (type III),
- a childproof white cap equipped with an inviolability ring, made in high density polyethylene ; fitted with a transparent low density polyethylene part inside (insert)
- a 3 mL syringe for oral use equipped with a tip cannula (transparent natural barrel made of polypropylene and white plunger made of high density polyethylene material)

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

Vm 15052/4125

9. DATE OF FIRST AUTHORISATION

16 April 2014

10. DATE OF REVISION OF THE TEXT

30 August 2019

Approved 30 August 2019