Ceva Animal Health Ltd
Telephone: 01494 781510
Website: www.ceva.com
Email: cevauk@ceva.com

Zodon 25 mg/ml oral solution for cats and dogs

Species:	Cats, Dogs
Therapeutic indication:	**Pharmaceuticals: Antimicrobials: Oral preparations:** Others
Active ingredient:	Clindamycin
Product:	Zodon 25 mg/ml oral solution for cats and dogs
Product index:	Zodon 25 mg/ml oral solution for cats and dogs

Qualitative and quantitative composition

One ml contains:

Clindamycin (as hydrochloride) 25 mg

Ethanol 96% (E1510) 72 mg

Pharmaceutical form

Clear, amber oral solution

Clinical particulars

Target species

Cats and dogs

Indications for use

Infections caused by clindamycin sensitive germs such as:

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*.

Contraindications

Clindamycin should not be administered to hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion in those species could cause severe digestive disorders. Do not use in cases of hypersensitivity to either clindamycin or lincomycin, or to any of the excipients.

Special warnings for each target species

None.

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 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 (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.

Adverse reactions

Vomiting and/or diarrhoea have been observed.

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.

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.

Interaction with other medicinal products 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.

Amounts to be administered and administration routes

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 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

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.

Overdose

High dose levels up to 300 mg/kg have been well tolerated in dogs without any adverse effects. 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.

Pharmacological particulars

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. Recent studies (2010) report an incidence between 25 to 40%..

Pharmacokinetic properties

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.

Pharmaceutical particulars

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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months

Shelf life after first opening the immediate packaging: 28 days

Special precautions for storage

Do not store above 30°C

Marketing Authorisation Number

Vm 15052/4126

Significant changes

Date of the first authorisation or date of renewal

16th April 2014

Date of revision of the text

May 2018

Any other information

Legal category

Legal category: POM-V

GTIN

GTIN description: Zodon 25 mg/ml oral solution for cats and dogs

GTIN: 03411112279951

Ceva Animal Health Ltd
Telephone: 01494 781510
Website: www.ceva.com
Email: cevauk@ceva.com

Zodon 88 mg and 264 mg Tablets for Dogs

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals: Antimicrobials: Oral preparations:** Tablets
Active ingredient:	Clindamycin
Product:	Zodon 88 mg and 264 mg Tablets for Dogs
Product index:	Zodon 88 & 264 mg Tablets for Dogs

Qualitative and quantitative composition

Zodon 88 mg Tablet: Each tablet contains: Clindamycin 88 mg

Zodon 264 mg Tablet: Each tablet contains: Clindamycin 264 mg

Pharmaceutical form

Chewable, clover-shaped scored beige tablet. The tablet can be divided into four equal parts

Clinical particulars

Target species

Dogs

Indications for use

For the treatment of infected wounds and abscesses, and oral cavity/dental infections, caused by or associated with *Staphylococcus* spp., *Streptococcus* spp. (except *Streptococcus faecalis*), *Bacteroides* spp., *Fusobacterium necrophorum*, and *Clostridium perfringens*.

For the treatment of superficial pyoderma associated with *Staphylococcus pseudintermedius*.

For the treatment of osteomyelitis, caused by *Staphylococcus aureus*.

Contraindications

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

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.

Special precautions for use in animals

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals. Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. 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.

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 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.

The use of the product is not recommended in suckling puppies.

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

People with known hypersensitivity to lincosamides (lincomycin and clindamycin) should avoid contact with the veterinary medicinal product. Wash hands after handling tablets. 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.

Adverse reactions

Vomiting and diarrhoea have occasionally been observed.

Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as *clostridia* and yeasts. In cases of superinfection, appropriate measures must be taken according to the clinical situation.

Use during pregnancy or lactation

While high dose studies in rats suggest 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 the blood-milk barrier. Treatment of lactating females can cause diarrhoea in puppies. Use the product only according to the benefit/risk assessment by the responsible veterinarian.

Interactions

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. The product should be used with caution in animals receiving such agents.

Clindamycin should not be combined with erythromycin or other macrolides to prevent macrolide-induced resistance to clindamycin.

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.

Amounts to be administered and administration route

For oral administration.

1. For the treatment of infected wounds and abscesses, and oral cavity/dental infections, administer either:

5.5 mg/kg of bodyweight every 12 hours for 7-10 days, or

11 mg/kg of bodyweight every 24 hours for 7-10 days

If no clinical response is seen within 4 days, redetermine the diagnosis.

2. For the treatment of superficial pyoderma in dogs, administer either:

5.5 mg/kg of bodyweight every 12 hours, or

11 mg/kg of bodyweight every 24 hours

Therapy of superficial pyoderma is usually recommended for 21 days, with extension of therapy based on clinical judgement.

3. For the treatment of osteomyelitis in dogs, administer:

11 mg/kg of bodyweight every 12 hours for a minimum of 28 days

If no clinical response is seen within 14 days, the treatment should be stopped and the diagnosis redetermined.

For example:

For a dose regimen of 11mg/kg

Weight (kg)	Zodon 88 mg No. tablets per administration	Weight (kg)	Zodon 264 mg No. tablets per administration
1.0-2.0	1/4	4.5-6.0	1/4
2.1-4.0	1/2	6.1-9.0	Use Zodon 88 mg
4.1-6.0	3/4	9.1-12.0	1/2
6.1-8.0	1	12.1-18.0	3/4
8.1-10.0	1 ¼	18.1-24.0	1
10.1-12.0	1 ½	24.1-30.0	1 ¼
12.1-14.0	1 ¾	30.1-36.0	1 ½
14.1-16.0	2	36.1-42.0	1 ¾
		42.1-48.0	2

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.

For a dose regimen of 5.5mg/kg

Weight (kg)	Zodon 88 mg Number of tablets per administration	Weight (kg)	Zodon 264 mg Number of tablets per administration
2.0-4.0	1/4	4.5-6.0	Use Zodon 88 mg
4.1-8.0	1/2	6.1-12.0	1/4
8.1-12.0	3/4	12.1-24.0	1/2
12.1-16.0	1	24.1-36.0	3/4
		36.1-48.0	1

The tablets are flavoured. They can be administered directly into the mouth of the animals or with a small quantity of food.

Overdose

In dogs, oral doses of clindamycin up to 300 mg/kg/day did not result in toxicity. Dogs receiving 600 mg/kg/day of clindamycin developed anorexia, vomiting and weight loss. In cases of

overdose, discontinue treatment immediately and establish symptomatic treatment.

Pharmacological particulars

Pharmacodynamic properties

Clindamycin is a semi-synthetic antibiotic produced by 7(S)-chloro substitution of the 7(R)-hydroxy group of the natural antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

Clindamycin acts by a bacteriostatic mechanism where the drug interferes with protein synthesis within the bacterial cell, thus inhibiting the growth and multiplication of the bacteria. Clindamycin binds to the 23S ribosomal RNA component of the 50S subunit. This prevents amino acids binding on these ribosomes, and therefore inhibits peptide bond formation.The ribosomal sites are close to those bound by macrolides, streptogramins or chloramphenicol.

Clindamycin is a moderate spectrum antimicrobial drug.

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.

Pharmacokinetic properties

Absorption: Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract following oral administration.

Serum values: After oral administration of 13.1 mg/kg bodyweight, the maximal plasma concentration of

6.4 µg/ml (Mean Cmax) is reached within 50 minutes (Mean Tmax). The biological plasma half-life of clindamycin in the dog is approximately 5 hours. No accumulation of bioactivity has been observed in dogs after several oral administrations.

Metabolism and Excretion: Extensive research of the metabolism and excretion pattern of clindamycin shows that the parent molecule as well as bioactive and bio-inactive metabolites are excreted via the urine and faeces. Nearly all bioactivity in the serum following oral administration is due to the parent molecule (clindamycin)

Pharmaceutical particulars

Shelf life

Shelf-life after first opening the immediate packaging: 72 hours

Special precautions for storage

Do not store above 30°C

Tablet portions should be stored in the blister pack. Any tablet portions remaining after 72 hours should be discarded. Keep the blister in the outer carton.

Marketing Authorisation Number

Zodon 88 mg Tablets: Vm 15052/4128

Zodon 150 mg Tablets Vm:15052/4126

Zodon 264 mg Tablets: Vm 15052/4127

Significant changes

Date of the first authorisation or date of renewal

22nd May 2014

Date of revision of the text

October 2016

Any other information

Legal category

Legal category: POM-V

GTIN

GTIN description: Zodon 88 mg Tablets

GTIN: 03411112276455

GTIN description: Zodon 264mg Tablets

GTIN: 03411112276479