# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zodon 264 mg chewable tablets for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
**Active substance:**
Clindamycin (as hydrochloride) .....264 mg

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Dogs.

### 4.2 Indications for use, specifying the target species

- For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, 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.*

### 4.3 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.

### 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

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 macrolide 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.

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.

## 4.6 Adverse reactions (frequency and seriousness)

Vomiting and diarrhoea have been reported very rarely.
Hypersensitivity reactions and thrombocytopenia have been reported very rarely.

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.
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 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.
The use of the product is not recommended in neonates.

## 4.8 Interaction with other medicinal products and other forms of interaction

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**.**

## 4.9 Amounts to be administered and administration route

For oral administration

1. For the treatment of infected wounds and abscesses, and oral cavity infections including periodontal disease, 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) | Number of tablets per administration |
|---|---|
| 4.5 – 6.0 | ¼ tab |
| 6.1 - 9.0 | Use Zodon 88 mg |
| 9.1 – 12.0 | ½ tab |
| 12.1 – 18.0 | ¾ tab |
| 18.1 – 24.0 | 1 tab |
| 24.1 – 30.0 | 1 + ¼ tabs |
| 30.1 – 36.0 | 1 + ½ tabs |
| 36.1 – 42.0 | 1 + ¾ tabs |
| 42.1 – 48.0 | 2 tabs |

- For a dose regimen of 5.5 mg/kg

| Weight (kg) | Number of tablets per administration |
|---|---|
| 4.5 – 6.0 | Use Zodon 88 mg |
| 6.1 – 12.0 | ¼ tab |
| 12.1 – 24.0 | ½ tab |
| 24.1 – 36.0 | ¾ tab |
| 36.1 – 48.0 | 1 tab |

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.
The tablets are flavoured. They can be administered directly into the mouth of the animals or with a small quantity of food.
Instruction on how to divide the tablet: Put the tablet on an even surface, with its scored side facing down (convex face up). With the tip of the forefinger, exert slight vertical pressure on the middle of the tablet to break it along its width into halves. Then, in order to obtain quarters, exert slight pressure on the middle of one half with the forefinger to break it into two parts.

### 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. 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

### 4.11 Withdrawal period(s)

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-infectives for systemic use, lincosamides
ATC Vet Code: QJ01FF01

### 5.1 Pharmacodynamic properties

**Mode of action**

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.

**Antibacterial spectrum**

Clindamycin is a moderate spectrum antimicrobial drug.

Susceptible microorganisms (S):
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 ≤0.5µg/ml; I=1-2µg/ml; R ≥ 4µg/ml. (CLSI July 2013).

**Type and mechanism of resistance**

Clindamycin belongs to the lincosamide group of antibiotics. Resistance can develop to the lincosamides alone, but more commonly cross-resistance occurs among macrolides, lincosamides and streptogramin B antibiotics ($MLS_B$ group). Resistance is the result of methylation of adenine residues in the 23S RNA of the 50S ribosomal subunit, which prevents drug binding to the target site. Different bacterial species are able to synthesize an enzyme, encoded by a series of structurally related erythromycin ribosomal methylase (*erm*) genes. In pathogenic bacteria, these determinants are mostly borne by plasmids and transposons that are self-transferable. The erm genes occur predominantly as variants erm(A) and erm(C) in *Staphylococcus aureus* and as variant erm(B) in *Staphylococcus pseudintermedius*, streptococci and enterococci. Bacteria resistant to macrolides but initially susceptible

to clindamycin, rapidly develop resistance to clindamycin when exposed to macrolides. These bacteria present a risk of *in vivo* selection of constitutive mutants.

$MLS_B$ inducible resistance is not detected by standard in vitro susceptibility testing methods. The CLSI recommends the D-zone test to be routinely performed in veterinary diagnostic laboratories in order to detect clinical isolates with inducible resistance phenotype. Clindamycin use should be discouraged in these patients.

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

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 $C_{max}$) is reached within 50 minutes (Mean $T_{max}$). 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)

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Chicken flavour
Yeast extract
Sodium croscarmellose
Copovidone
Magnesium stearate
Silica, colloidal anhydrous
Microcrystalline cellulose
Lactose monohydrate

### 6.2 Major Incompatibilities

Not applicable

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life for tablet portions after first opening the immediate packaging: 72 hours (or 3 days)

### 6.4 Special precautions for storage

Do not store above 30°C
Tablet portions should be stored in the blister pack
Keep the blister in the outer carton.

### 6.5 Nature and composition of immediate packaging

Blister pack: (PVC – TE –PVDC – aluminium heat sealed) containing 6 tablets per blister

Cardboard box of 6 tablets containing 1 blister of 6 tablets
Cardboard box of 12 tablets containing 2 blisters of 6 tablets
Cardboard box of 96 tablets containing 16 blisters of 6 tablets
Cardboard box of 120 tablets containing 20 blisters of 6 tablets
Cardboard box of 240 tablets containing 40 blisters of 6 tablets
Not all pack sizes may be marketed.

### 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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

## 8. MARKETING AUTHORISATION NUMBER

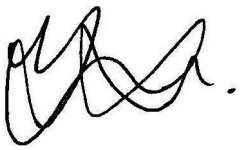
Vm 15052/4127

## 9. DATE OF FIRST AUTHORISATION

22 May 2014

## 10. DATE OF REVISION OF THE TEXT

October 2022



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