1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bioclindavet 275 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Clindamycin 275 mg
(equivalent to 298.62 mg Clindamycin hydrochloride)

Excipients:

Qualitative composition of excipients and other constituents
Croscarmellose sodium
Cellulose, microcrystalline
Lactose monohydrate
Silica, colloidal hydrated
Copovidone
Meat flavour
Magnesium stearate

Off-white with brown spots, round and convex tablet with a cross-shaped break line on one side; 275mg (16mm diameter). The tablet can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

- For the treatment of infected wounds, abscesses and oral cavity/dental infections caused by or associated with clindamycin-susceptible species of *Staphylococcus* spp., *Streptococcus* spp., *Bacteroides* spp., *Fusobacterium necrophorum*, *Clostridium perfringens*.
- For the treatment of osteomyelitis caused by *Staphylococcus aureus*.

3.3 Contraindications

Do not use in hamsters, guinea pigs, rabbits, chinchillas, horses or ruminants because clindamycin ingestion by these species may cause severe gastrointestinal disorders which may result in death.
Do not use in cases of hypersensitivity to either clindamycin or lincomycin, or to any of the excipients.

3.4 Special warnings

Cross-resistance has been shown between clindamycin and different antimicrobials belonging to lincosamides and macrolides classes (including erythromycin).
Use of clindamycin should be carefully considered when susceptibility testing has shown resistance to lincosamides and macrolides because its effectiveness may be reduced.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s) including the D-zone test.
If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at local/regional level.
Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.
Clindamycin is likely to favour the proliferation of non-susceptible organisms such as resistant C*lostridia* spp. and yeasts. In case of secondary infection, appropriate corrective measures should be taken based on clinical observations.
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 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 veterinary medicinal product is not recommended in neonates.
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands carefully after use.
This veterinary medicinal product may cause hypersensitivity (allergic reaction). 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.
To avoid accidental ingestion, particularly by a child, do not take the tablets out of the blister until ready to administer to the animal, unused tablet parts should be returned to the open blister space, inserted back into the carton, used at the subsequent administration and kept in a safe place out of the sight and reach of children.
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.
To limit the risk related to residues and resistant bacteria, general hygiene precautions must be implemented. Hand washing with soap and water is particularly recommended when handling treated animals, their waste, and their bedding.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Undetermined frequency (cannot	Vomiting and/or diarrhoea

be estimated from the available data)	

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 has not been established.
The safety of the veterinary medicinal product in breeding male dogs has not been established.

Pregnancy and lactation:
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.

Fertility:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 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. Veterinary medicinal 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.

3.9 Administration routes and dosage

For oral use.

Recommended dose:

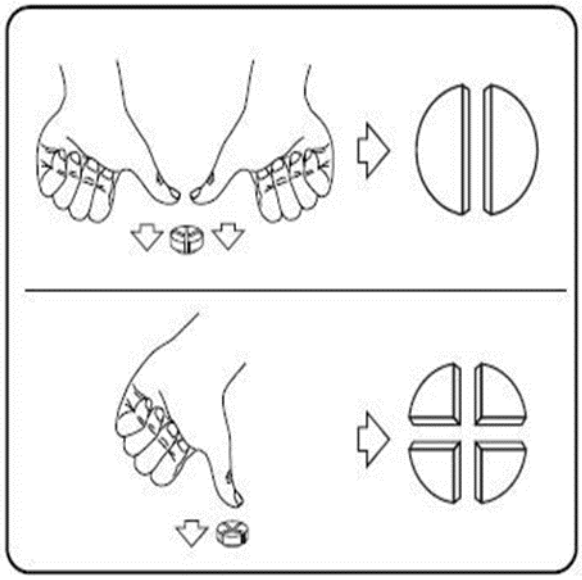
- Infected wounds, abscesses and oral cavity/dental infections: 11 mg clindamycin per kg of bodyweight per 24 hours for a maximum of 28 days. The duration of treatment depends on the decision of the responsible veterinarian.
- Treatment of bone infections (osteomyelitis): 11 mg clindamycin per kg of body weight per 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.

Example :
- For a dose regimen of 11 mg/kg :

BIOCLINDAVET 275 mg	
Weight (kg)	**Number of tablets per**

	administration
5 – 6.25	¼ tablet
6.3 – 9.40	Use Bioclindavet 75 mg
9.5 – 12.50	½ tablet
12.6 – 18.75	¾ tablet
18.8 – 25.00	1 tablet
25.1 – 31.25	1 + ¼ tablets
31.3 – 37.50	1 + ½ tablets
37.6 – 43.75	1 + ¾ tablets
43.8 – 50.00	2 tablets

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Tablets can be divided into 2 or 4 equal parts to ensure accurate dosage.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.

Halves: press down with your thumbs on both sides of the tablet.
Quarters: press down with your thumb in the middle of the tablet.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 (AST/SGOT and ALT/SGPT) have been observed occasionally.
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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01FF01.

4.2 Pharmacodynamics

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.
Resistance to lincosamides alone can occur, but cross-resistance with macrolides, lincosamides, and streptogramins B (MLS group B) is more common. Resistance results from methylation of adenine residues on the 23S RNA of the 50S ribosomal subunit, which prevents the antibiotic from binding to the target site. Different bacterial species are capable of synthesizing an enzyme, encoded by various structurally related erm (erythromycin ribosomal methylase) genes. In pathogenic bacteria, these determinants are primarily carried by plasmids and self-transferring transposons. The erm genes are predominantly present as the erm(A) and erm(C) variants in *Staphylococcus aureus* and as the erm(B) variant 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 pose a risk of in vivo selection of constitutive mutants.
CLSI clindamycin veterinary breakpoints are available in *Staphylococcus* spp. and *Streptococci*-ß-haemolytic group isolates from dogs with skin and soft tissue infections: S ≤0.5µg/ml; I=1-2µg/ml; R≥4µg/ml (CLSI 2020).
The incidence of resistance to lincosamides in *Staphylococcus* spp. appears to be wide-ranging in
Europe with a weighted arithmetic mean of resistance about 25% in *Staphylococcus pseudintermedius* and in *Staphylococcus aureus* (EFSA, 2021).

4.3 Pharmacokinetics

Clindamycin is almost completely absorbed after oral administration.
After oral administration of the veterinary medicinal product at a dose of 11 mg/kg, maximum plasma concentrations of 5.7 µg/ml are reached within 1 hour.
Clindamycin is widely distributed and may concentrate in some tissues.
The mean elimination half-life of clindamycin is around 6 hours.
Approximately 70% is excreted in faeces and 30% in the urine.
Clindamycin is approximately 93% bound to plasma proteins.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

This veterinary medicinal product requires no special storage conditions.

5.4 Nature and composition of immediate packaging

PVC/PE/PVDC (white) – Alu blisters, containing 10 tablets each.

Package sizes:
Cardboard box of 10 tablets (1 blisters of 10 tablets).
Cardboard box of 30 tablets (3 blisters of 10 tablets).
Cardboard box of 100 tablets (10 blisters of 10 tablets).
Cardboard box of 250 tablets (25 blisters of 10 tablets).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Axience

7. MARKETING AUTHORISATION NUMBERS

VPA22873/004/002

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01/10/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).