

Veterinary medicine package leaflet

This medicine is supplied on veterinary prescription only
For use in animals only

1. Name, form, and strength of the veterinary medicine

Clinacin Veterinary Tablets 300 mg Clinacin Veterinary Tablets 75 mg

2. Active ingredient

Each Clinacin veterinary tablet 300 mg contains:
300 mg of Clindamycin (as Clindamycin Hydrochloride).

Each Clinacin veterinary tablet 75 mg contains:
75 mg of Clindamycin (as Clindamycin Hydrochloride).

For a list of inactive ingredients and allergens see section 11: 'Additional information'.

3. What is this medicine intended for?

Antibiotic tablets for use in dogs to treat infected wounds, abscesses, pyoderma and oral cavity/dental infections caused by or associated with clindamycin-sensitive bacteria (Staphylococci, Streptococci, Bacteroidaceae, Fusobacterium necrophorum, Clostridium perfringens) and to treat osteomyelitis caused by Staphylococcus aureus. Clinacin can also be used to help provide antimicrobial cover during dental procedures.

Therapeutic group: Lincosamides.

4. Contraindications

Clinacin veterinary tablets are contra-indicated in animals that are hypersensitive to clindamycin or lincomycin preparations.

Do not administer to rabbits, guinea pigs, chinchillas, hamsters, horses or ruminants.

Do not use clindamycin concomitantly with chloramphenicol or macrolides as they may antagonise each other at their target site.

5. Side effects

Clinacin sometimes causes the overgrowth of non-sensitive organisms such as drug-resistant clostridia and yeasts. In cases of superinfection, suitable measures must be taken based on the clinical condition. Vomiting and diarrhea have been observed occasionally.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

6. Target animal

Dogs.

7. Route of administration and dose

Route of administration: oral.

Dose:

Dental infections, wounds and abscesses:

When treating infected wounds, abscesses, oral cavity/dental infections, administer 5.5 mg/kg bodyweight every 12 hours for seven to ten days. Based on clinical evaluation, treatment can be extended to a maximum of 28 days. If no improvement is seen within four days, the pathogen's sensitivity to the medicine must be re-evaluated. To help provide antimicrobial cover during dental procedures, a ten day course of 5.5 mg/kg bodyweight every 12 hours is recommended. Start this course of treatment five days before the planned dental procedure and continue for five days after it.

Superficial pyoderma:

To treat superficial pyoderma administer 11 mg/kg bodyweight every 24 hours. Continue giving the treatment for at least 21 days.

Osteomyelitis (inflammation of the bones):

To treat osteomyelitis, administer 11 mg/kg bodyweight every 12 hours for 28 days. If there is no improvement within 14 days, the pathogen's sensitivity to the medicine must be re-evaluated.

Dosage table:

Dental infections, wounds, abscesses	Superficial pyoderma	Osteomyelitis
5.5 mg/kg twice a day	11 mg/kg once a day	11 mg/kg twice a day

8. Warnings

- **Special warnings about using in the target animal**

Clindamycin and lincomycin show parallel resistance.

There is partial cross-resistance of clindamycin to erythromycin and other macrolide antibiotics.

Before using clindamycin tablets, the pathogen must be identified and its susceptibility to clindamycin should be established.

Neuromuscular blocking effects have been observed with clindamycin possibly leading to an increase of efficacy of other neuromuscular blocking agents. Use clindamycin tablets with caution when treating animals who are receiving such agents.

During prolonged therapy of one month or longer, periodic liver and kidney function tests and blood counts must be performed. Use caution when determining the dose for patients with severe renal and/or liver function disorders accompanied by severe metabolic impairment, and monitor their condition by serum tests during high-dosage treatment with clindamycin.

Bioavailability of the product is higher in fasting dogs compared to non-fasting dogs.

- **Pregnancy and lactation**

Although high-dose studies of clindamycin in mice show that clindamycin is not teratogenic and does not significantly affect male and female fertility, its safety in gestating bitches and fertile males has not been established. Therefore, the veterinarian must assess the benefit against the risk of administering the medicine during pregnancy and lactation.

- **Overdose**

Symptoms of overdose include vomiting, inappetence (not eating), and diarrhea. In such cases, treatment should be stopped immediately and the dogs treated symptomatically.

9. Storage instructions

- **Prevent poisoning!** To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants.
- Do not use after the expiry date (Exp. Date) stated on the package. The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original package. Do not use this medicine after the expiry date stated on the label and carton.
- Use this medicine within 50 days of first opening.

10. Instructions for disposing of the medicine/remaining medicine after use

Any unused veterinary medicine or waste from such veterinary medicines must be disposed of according to local regulations.

11. Additional information

- In addition to the active ingredient this medicine also contains: Ludipress (Lactose monohydrate, Povidone and Crospovidone), Microcrystalline cellulose, Sodium lauryl sulphate, Colloidal silicon dioxide, Magnesium stearate.
- What the medicine looks like and what are the contents of the package: Clinacin 75 mg tablets are packaged in white HDPE vials with a childproof cap, and contain 10, 16, 20, 30, 50, 80, or 100 tablets. Clinacin 300 mg tablets are packaged in white HDPE vials with a childproof cap, and contain 6, 10, 14, 16, 20, 28, 30, 42, 50, 56, 60, 70, 80, 84, 98, 100, or 200 tablets.
Not all pack sizes may be available.

- **Manufacturer:**

Chanelle Pharmaceuticals Manufacturing Ltd., Dublin Road, Loughrea, Co. Galway, Ireland.

- **Registration holder and importer:**

A.L. Medi-Market Ltd., 18 Hakadar St., Netanya 42138.

- **Medicine registration number in the National Medicines Registry of the Ministry of Health:**

Clinacin veterinary tablets 75 mg: 158-64-34770-00

Clinacin veterinary tablets 300 mg: 158-65-34771-00

This leaflet was reviewed and approved by the Ministry of Health in: June 2017.