PACKAGE LEAFLET

For animal treatment only

CLINDAVET 75 mg

clindamycin tablets 75mg for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:
PROVET S.A.
120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece
Tel.: +30 2105508500, +30 2105575770-3
E-mail: vet@provet.gr

Manufacturer responsible for batch release:
PROVET S.A. (FACTORY)
Nikiforou Foka & Agion Anargyron, Thesi Vrago,
193 00 Aspropyrgos, Attiki, Greece

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLINDAVET tablets
Tablets
Clindamycin 75 mg/tab
for Dogs

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1 tablet contains:
Active substance: Clindamycin base (as hydrochloride) 75 mg
Excipients: Talc, Sodium Lauryl Sulfate, Magnesium Stearate, Aerosil 200, Prezelatinized Starch, Lactose.

4. INDICATIONS

CLINDAVET tablets 75mg is indicated for the treatment of infected wounds, abscesses and infections of the mouth-cavity and teeth caused by *Staphylococcus* spp., *Streptococcus* spp. (except *Enterococcus faecalis*), *Bacteroides* spp., *Fusobacterium necrophorum* and *Clostridium perfringens*.
It is also recommended for the treatment of osteomyelitis caused by *Staphylococcus aureus*. Can also be used to help provide antimicrobial cover during dental operations.

Before treatment with CLINDAVET tablets 75mg pathogens should be identified and sensitivity to clindamycin should be confirmed.

5. CONTRAINDICATIONS

Do not use in case of known hypersensitivity to clindamycin or lincomycin.
Because of possible gastro-intestinal side-effects do not administer to rabbits, hamsters, chinchillas, guinea pigs, horses or ruminating animals.

6. ADVERSE REACTIONS

Clindamycin sometimes causes the overgrowth of non-sensitive microorganisms as some clostridia and yeasts. In case of super infection appropriated measures must be taken according to the clinical situation. Vomiting and diarrhoea have occasionally been observed.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES
Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION
Oral administration.
Infected wounds, abscesses, infected mouth-cavity and dental infections:
5.5 mg/kg every 12 hours for 7 to 10 days.
Treatment may be extended to a maximum of 28 days based on clinical judgement.
If no clinical response is seen within 4 days, re-determine the diagnosis.
Osteomyelitis
11 mg/kg 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 re-determined.

Bodyweight	**Infected wounds, abscesses, infected mouth-cavity and dental infections (5.5 mg/kg bodyweight, every 12 hours)**	**Osteomyelitis (11 mg/kg bodyweight, every 12 hours)**
13.5 kg	1 X 75 mg, twice daily	2 X 75 mg, twice daily

9. ADVICE ON CORRECT ADMINISTRATION
None

10. WITHDRAWAL PERIOD
Not applicable

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS
Clindamycin and erythromycin show cross-resistance. Partial cross-resistance has been demonstrated between clindamycin, erythromycin and macrolide-antibiotics.
During prolonged canine osteomyelitis therapy or one month or greater, periodic liver and kidney function tests and blood should be performed.
Patients with severe renal and/or hepatic disturbances should be dosed with caution and should be monitored by serum examination during high dose clindamycin therapy.

Special precautions for use in animals
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Not applicable.

Pregnancy and Lactation:
Laboratory studies in rats showed no evidence of teratogenic or fetotoxic effects on female and male dogs. The safety of the veterinary medicinal product has not been established during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Clindamycin hydrochloride has been shown to induce neuromuscular blockade and enhance the muscular relaxation caused by the non-depolarizing relaxants. The use of CLINDAVET tablets 75mg must be used with caution in animals receiving agents of this specific category.
Clindamycin should not be used simultaneously with chloramphenicol and macrolides because of their mutual antagonism in the place of action - 50S ribosomal subunit.

Overdose (symptoms, emergency procedures, antidotes):
The maximum dosage, which is well tolerated orally is 300 mg/kg bodyweight. This is 30 times the indicated dosage for infected wounds, abscesses, infected mouth-cavity and dental infections.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

JUNE 2021

15. OTHER INFORMATION

PACKAGES
Carton box containing 20 tablets (2 blisters x 10 tabs)
Carton box containing 100 tablets (25 blisters x 4 tabs)
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

under veterinary medical prescription

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN