

For the use of Registered Veterinary Practitioner, Hospital or Laboratory

BIOCLAN

(Clindamycin 150mg, 300mg, 600mg Tablets and Oral Solution)

Composition

Each uncoated tablet of BIOCLAN 150 contains:

Clindamycin Hydrochloride USP 150 mg

Colours: Iron Oxide Red NF

Each uncoated tablet of BIOCLAN 300 contains:

Clindamycin Hydrochloride USP 300 mg

Colours: Iron Oxide Red NF

Each uncoated tablet of BIOCLAN 600 contains:

Clindamycin Hydrochloride USP 600 mg

Colours: Iron Oxide Red NF

Each ml of BIOCLAN Oral Solution contains:

Clindamycin Hydrochloride

Eq. to Clindamycin USP 25mg

Excipients q.s.

Isopropyl alcohol q.s.

Category: Anti-bacterial

Pharmacology

Pharmacodynamics

Clindamycin inhibits bacterial protein synthesis at the ribosomal (50s sub-unit) level.

Pharmacokinetics

Absorption:

Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract following oral administration. Effective clindamycin antibacterial serum levels are reached within 30 minutes following administration of the therapeutic dose.

Serum values:

Therapeutic serum levels of clindamycin can be maintained by oral administration of 5.5 mg/kg bodyweight every 12 hours or 11 mg/kg bodyweight every 24 hours; peak serum concentrations are on average reached 75 minutes after oral administration. 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 is excreted *via* the urine and faeces. Nearly all bioactivity in the serum following oral administration is due to the parent molecule (clindamycin).

Indications:

Clindamycin uncoated tablet are indicated for use in dogs as follows:

- For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections, caused by or associated with *Staphylococcus* spp, *Streptococcus* spp (except *Streptococcus faecalis*), *Bacteroides* spp, *Fusobacterium necrophorum*, and *Clostridium perfringens*. To help provide antimicrobial cover during dental procedures.
- For the treatment of superficial pyoderma associated with *Staphylococcus intermedius*.
- For the treatment of osteomyelitis, caused by *Staphylococcus aureus*.
- Before Clindamycin therapy is initiated, the involved pathogens should be identified and sensitivity to clindamycin established.

Dosage and Administration:

For oral administration only.

1. For the treatment of infected wounds and abscesses, and infected mouth cavity and dental infections in dogs, 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. To help provide antimicrobial cover during dental procedures, a 10 day course is recommended. This should be initiated five days before dental therapy and continued for five days thereafter. In dogs, treatment may be extended to a maximum of 28 days based on clinical judgment.

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

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.

Dosage table:

Body weight	Superficial pyoderma	Dental infections, wounds and abscesses	Osteomyelitis
	5.5 mg/kg/12 h (21 days)	11 mg/kg/24 h (7-10 days)	11 mg/kg/12 h (28 days)
4.5 kg	50mg in 2 divided dose or 50mg od		25 mg bid
13.5 kg	150 mg in 2 divided dose or 150mg od		150 mg bid
27.0 kg	300mg in 2 divided dose or 300mg bid		300 mg bid
54.0 kg	600mg in 2 divided dose or 600mg od		600 mg bid

Recommended dose in Cats:

While using BIOCLAN tablets, 5mg/kg twice daily or 10mg/kg once daily

In Toxoplasmosis, 25mg/kg every day for 7-10 days

While using BIOCLAN Oral Solution, 1-3ml/2.5kg twice a day

Contraindications and Warnings:

Do not use in animals that are hypersensitive to preparations containing clindamycin or lincomycin.

Do not administer to rabbits, hamsters, guinea pigs, chinchillas, horses or ruminants because ingestion of clindamycin by these species may result in severe gastrointestinal disturbance.

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.

Vomiting and diarrhoea have occasionally been observed. Clindamycin sometimes causes the overgrowth of non-sensitive organisms such as resistant clostridia and yeasts. In cases of superinfection, appropriate measures must be taken according to the clinical situation.

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

Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they antagonize each other at their site of action at the 50S ribosomal sub-unit.

Pregnancy and Lactation:

Safety in gestating bitches or breeding male dogs has not been established.

Interactions:

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

Clindamycin should not be used concomitantly with chloramphenicol or macrolides as they antagonize each other at their site of action at the 50S ribosomal sub-unit.

Adverse Drug Reactions:

Vomiting and diarrhoea have occasionally been observed.

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

Overdosage: None known

Presentation: Blister of 10 tablets

Storage: Store in a cool and dry place.

Keep out of reach of children.



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