Clindamycin Hydrochloride Tablets

Felixvet Inc.

For use in dogs only

Clindamycin Hydrochloride Tablets (for use in dogs only) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

Dogs: Skin infections (wounds and abscesses) due to coagulase positive staphylococci *(Staphylococcus aureus* or *Staphylococcus intermedius).*
Deep wounds and abscesses due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.*
Dental infections due to *Staphyloccus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.*
Osteomyelitis due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens.*

Product	Strength	Pack Size
Clindamycin Hydrochloride Tablets	25 mg	400 Tablets
	75 mg	200 Tablets
	150 mg	100 Tablets

Features and benefits

- Therapeutically equivalent to the pioneer drug, the same safety and efficacy.
- Tablets are available in three strengths - 25, 75 and 150 mg.
- Each tablet is scored for easy/accurate dosing.

Clindamycin Hydrochloride Tablets

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Caution

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Clindamycin Hydrochloride Tablets contain clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisyntheic antibiotic produced by a 7(S)- chlorosubstitution of the 7(R)-hydroxyl group of a naturally produced antibiotic produced by *Streptomyces lincolnensis var. lincolnensis*.

Clindamycin Hydrochloride Tablets (For Use in Dogs Only):

25 mg Tablet, each white to off white colored round shaped tablet contains clindamycin hydrochloride equivalent to 25 mg of clindamycin.

75 mg Tablet, each white to off white colored round shaped tablet contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

150 mg Tablet, each white to off white colored round shaped tablet, contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

CLINICAL PHARMACOLOGY

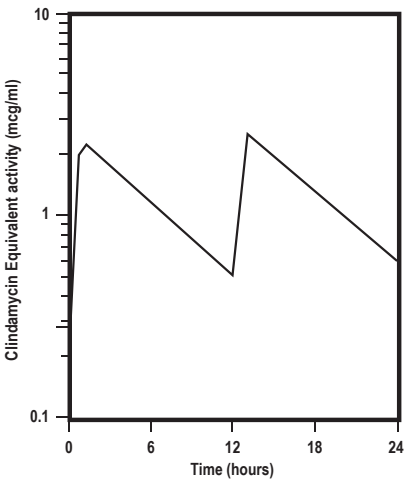
Absorption

Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract.

Dog Serum Levels

Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 2.5 mg/lb of clindamycin hydrochloride every 12 hours. This same study revealed that average peak serum concentrations of clindamycin occur 1 hour and 15 minutes after oral dosing. The elimination half-life for clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

Clindamycin Serum Concentrations
2.5 mg/lb (5.5 mg/kg) After B.I.D. Oral
Dose of Clindamycin Hydrochloride Capsules to Dogs



Metabolism and Excretion

Extensive studies of the metabolism and excretion of clindamycin hydrochloride administered orally in animals and humans have shown that unchanged drug and bioactive and bioinactive metabolites are excreted in urine and feces. Almost all of the bioactivity detected in serum after clindamycin hydrochloride product administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-demethyl clindamycin and clindamycin sulfoxide.

Site and Mode of Action

Clindamycin is an inhibitor of protein synthesis in the bacterial cell. The site of binding appears to be in the 50S sub-unit of the ribosome. Binding occurs to the soluble RNA fraction of certain ribosomes, thereby inhibiting the binding of amino acids to those ribosomes. Clindamycin differs from cell wall inhibitors in that it causes irreversible modification of the protein- synthesizing subcellular elements at the ribosomal level.

Microbiology

Clindamycin is a lincosaminide antimicrobial agent with activity against a wide variety of aerobic and anaerobic bacterial pathogens. Clindamycin is a bacteriostatic compound that inhibits bacterial protein synthesis by binding to the 50S ribosomal sub-unit. The minimum inhibitory concentrations (MICs) of Gram-positive and obligate anaerobic pathogens isolated from dogs in the United States are presented in Table 1. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the Clinical and Laboratory Standards Institute (CLSI).

Table 1. Clindamycin MIC Values (µg/mL) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. during 1998-99[1]

Organism	Number of Isolates	MIC_{50}	MIC_{85}	MIC_{90}	Range
Soft Tissue/Wound[2]					
Staphylococcus aureus	17	0.5	0.5	≥4.0	0.25 - ≥4.0
Staphylococcus intermedius	28	0.25	0.5	≥4.0	0.125 - ≥4.0
Staphylococcus spp.	18	0.5	0.5	≥4.0	0.25 - ≥4.0
Beta-hemolytic streptococci	46	0.5	0.5	≥4.0	0.25 - ≥4.0
Streptococcus spp.	11	0.5	≥ 4.0	≥4.0	0.25 - ≥4.0
Osteomyelitis/Bone[3]					
Staphylococcus aureus	20	0.5	0.5	0.5	0.5[4]
Staphylococcus intermedius	15	0.5	≥4.0	≥4.0	0.25 - ≥4.0
Staphylococcus spp.	18	0.5	≥4.0	≥4.0	0.25 - ≥4.0
Beta-hemolytic streptococci	21	0.5	2.0	2.0	0.25 - ≥4.0
Streptococcus spp.	21	≥ 4.0	≥4.0	≥4.0	0.25 - ≥4.0
Dermal/Skin[5]					
Staphylococcus aureus	25	0.5	≥4.0	≥4.0	0.25 - ≥ 4.0
Staphylococcus intermedius	48	0.5	≥4.0	≥4.0	0.125 - ≥ 4.0
Staphylococcus spp.	32	0.5	≥4.0	≥4.0	0.25 - ≥ 4.0
Beta-hemolytic streptococci	17	0.5	0.5	0.5	0.25 - 0.5

[1]The correlation between the *in vitro* susceptibility data and clinical response has not been determined.
[2]Soft Tissue/Wound: includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass
[3]Osteomyelitis/Bone: includes samples labeled bone, fracture, joint, tendon
[4]No range, all isolates yielded the same value
[5]Dermal/Skin: includes samples labeled skin, skin swab, biopsy, incision, lip

INDICATIONS

Clindamycin Hydrochloride Tablets (for use in dogs only) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

Dogs : Skin infections (wounds and abscesses) due to coagulase positive staphylococci *(Staphylococcus aureus* or *Staphylococcus intermedius)*. **Deep wounds and abscesses** due to *Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

Dental infections due to *Staphyloccus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*. **Osteomyelitis** due to *Staphylococcus aureus, Bacteroides fragilis, Prevotella melaninogenicus, Fusobacterium necrophorum* and *Clostridium perfringens*.

CONTRAINDICATIONS

Clindamycin Hydrochloride Tablets are contraindicated in animals with a history of hypersensitivity to preparations containing clindamycin or lincomycin.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals.

WARNINGS

Keep out of reach of children. Not for human use.

Keep Clindamycin Hydrochloride Tablets in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

PRECAUTIONS

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

The use of clindamycin hydrochloride occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of Clindamycin Hydrochloride Tablets should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see **CONTRAINDICATIONS**). Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

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

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

ADVERSE REACTIONS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea.

CONTACT INFORMATION

To report suspected adverse drug experiences, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Felix Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

DOSAGE AND ADMINISTRATION

Dogs: Infected Wounds, Abscesses, and Dental Infections

Oral: 2.5-15.0 mg/lb body weight every 12 hours

Duration: Treatment with Clindamycin Hydrochloride Tablets may be continued up to a maximum of 28 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three or four days if no response to therapy is seen.

Dosage Schedule

Tablets

Clindamycin Hydrochloride Tablets 25 mg, administer 1-6 tablets every 12 hours for each 10 pounds of body weight.

Clindamycin Hydrochloride Tablets 75 mg, administer 1-6 tablets every 12 hours for each 30 pounds of body weight.

Clindamycin Hydrochloride Tablets 150 mg, administer 1-6 tablets every 12 hours for each 60 pounds of body weight.

Dogs: Osteomyelitis

Oral: 5.0-15.0 mg/lb body weight every 12 hours

Duration: Treatment with Clindamycin Hydrochloride Tablets is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen.

Dosage Schedule

Tablets

Clindamycin Hydrochloride Tablets 25 mg, administer 2-6 tablets every 12 hours for each 10 pounds of body weight.

Clindamycin Hydrochloride Tablets 75 mg, administer 2-6 tablets every 12 hours for each 30 pounds of body weight.

Clindamycin Hydrochloride Tablets 150 mg, administer 2-6 tablets every 12 hours for each 60 pounds of body weight.

ANIMAL SAFETY SUMMARY

Rat and Dog Data: One year oral toxicity studies in rats and dogs at doses of 30, 100 and 300 mg/kg/day (13.6, 45.5 and 136.4 mg/lb/day) have shown clindamycin hydrochloride capsules to be well tolerated. Differences did not occur in the parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls. Rats administered clindamycin hydrochloride at 600 mg/kg/day (272.7 mg/lb/day) for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day (272.7 mg/lb/day) vomited, had anorexia, and subsequently lost weight. At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gallbladder.

Safety in gestating bitches or breeding males has not been established.

STORAGE

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F) [see USP Controlled Room Temperature].

HOW SUPPLIED

Clindamycin Hydrochloride Tablets are available as:

- 25 mg - bottles of 400
- 75 mg - bottles of 200
- 150 mg - bottles of 100

NDC Number	Tablet Size	Tablets/Bottle
86101-052-18	25 mg	400
86101-053-15	75 mg	200
86101-054-11	150 mg	100

Approved by FDA under ANADA # 200-813

Distributed By:
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Manufactured in India

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