

# Clindamycin Hydrochloride Oral Drops

(clindamycin hydrochloride oral solution)

**R<sub>x</sub>**



- **Approved by FDA under ANADA # 200-398**
- **Clindamycin Hydrochloride Oral Drops is approved by the FDA as equivalent to the pioneer product Antirobe Aquadrops®<sup>1</sup>**
- **For use in dogs and cats**
- **Indicated for dental, deep wound and bone infections**
- **Clindamycin concentrates at the infections site and maintains high concentrations to combat susceptible anaerobic and aerobic bacteria**
- **Calibrated dropper for dosing accuracy**

For therapy of wounds, abscesses and dental infections, administer orally. Please consult package insert for full product information (see back page).


Size	Reorder No.	Lbs/Case	Case Pack
20 mL (0.68 fl oz)	OM090	2 lbs.	12 x 1

**RECOMMENDED DOG DOSAGE:** For therapy of wounds, abscesses and dental infections, orally administer 2.5 - 15.0 mg/lb (1-6 mL/10 lbs) body weight every 12 hours. For therapy of osteomyelitis orally administer 5.0 - 15.0 mg/lb (2-6 mL/10 lbs) body weight every 12 hours.

**RECOMMENDED CAT DOSAGE:** For therapy of wounds, abscesses and dental infections, orally administer 1 - 3 mL/5 lbs body weight once every 24 hours depending on the severity of the condition. See package insert for complete product information.

Rev. 10-22

TAKE TIME  OBSERVE LABEL DIRECTIONS  
Priority Care is a registered trademark of First Priority, Inc.

Priority Care  NDC# 58829-309-20  
**Clindamycin Hydrochloride Oral Drops**

(clindamycin hydrochloride oral solution)

Approved for use in dogs and cats.

**Equivalent to 25 mg per mL clindamycin**

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

Not For Use in Humans • Keep Out of Reach of Children

Net Contents: 20 mL (0.68 fl oz)

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**ACTIVE INGREDIENT:** Each mL contains: Clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

**WARNINGS:** Not for use in humans. Keep out of reach of children. To obtain a Safety Data Sheet(s), contact First Priority, Inc. at (800) 650-4899 or [www.prioritycare.com](http://www.prioritycare.com). Keep Clindamycin Hydrochloride Oral Drops in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

**STORAGE:** Store at controlled room temperature between 20° to 25°C (68° to 77°F) [see USP].

Keep container tightly closed when not in use.

Lot No. Exp. Date

Reorder No. OM090PC

Made in U.S.A.

Manufactured By:  
FIRST PRIORITY, INC., Elgin, IL 60123

[www.prioritycare.com](http://www.prioritycare.com)

<sup>1</sup> Antirobe Aquadrops is a registered trademark of Zoetis Services LLC, Parsippany, NJ

For a complete list of Priority Care distributors, please call our Customer Service Department at: 1-800-650-4899, or visit our Website: [www.prioritycare.com](http://www.prioritycare.com)

# Clindamycin Hydrochloride Oral Drops

(clindamycin hydrochloride oral solution)

Approved for use in dogs and cats.

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

## DESCRIPTION

Clindamycin Hydrochloride Oral Drops (clindamycin hydrochloride oral solution) contains clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic 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 Oral Drops (For Use in Dogs and Cats) is a palatable formulation intended for oral administration. Each mL of Clindamycin Hydrochloride Oral Drops contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

## INDICATIONS

Clindamycin Hydrochloride Oral Drops (for use in dogs and cats) is 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 melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*. **Dental infections** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*. **Osteomyelitis** due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenica*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

**Cats: Skin infections (wounds and abscesses)** due to *Staphylococcus aureus*, *Staphylococcus intermedius* and *Streptococcus* spp. **Deep wounds and abscesses** due to *Clostridium perfringens* and *Bacteroides fragilis*. **Dental infections** due to *Staphylococcus aureus*, *Staphylococcus intermedius*, *Streptococcus* spp., *Clostridium perfringens* and *Bacteroides fragilis*.

## 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 Oral Drops 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:

#### Oral Solution

Clindamycin Hydrochloride Oral Drops, administer 1-6 mL/10 lbs body weight every 12 hours.

### Cats:

#### Osteomyelitis

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

**Duration:** Treatment with Clindamycin Hydrochloride Oral Drops 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:

#### Oral Solution

Clindamycin Hydrochloride Oral Drops, administer 2-6 mL/10 lbs body weight every 12 hours.

### Cats:

**Infected Wounds, Abscesses and Dental Infections**

**Oral:** 5.0 - 15.0 mg/lb body weight once every 24 hours depending on the severity of the condition.

**Duration:** Treatment with Clindamycin Hydrochloride Oral Drops may be continued up to a maximum of 14

### Osteomyelitis/Bone<sup>1</sup>

Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>90</sub>	Range
<i>Staphylococcus aureus</i>	20	0.5	0.5	0.5*
<i>Staphylococcus intermedius</i>	15	0.5	≥4.0	0.25-≥4.0
<i>Staphylococcus</i> spp.	18	0.5	≥4.0	0.25-≥4.0
Beta-hemolytic streptococci	21	0.5	2.0	0.25-≥4.0
<i>Streptococcus</i> spp.	21	≥4.0	≥4.0	0.25-≥4.0

### Dermal/Skin<sup>1</sup>

Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>90</sub>	Range
<i>Staphylococcus aureus</i>	25	0.5	≥4.0	0.25-≥4.0
<i>Staphylococcus intermedius</i>	48	0.5	≥4.0	0.125-≥4.0
<i>Staphylococcus</i> spp.	32	0.5	≥4.0	0.25-≥4.0
Beta-hemolytic streptococci	17	0.5	0.5	0.25-0.5

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

**Table 2. Clindamycin MIC Values (µg/mL) from Diagnostic Laboratory Survey Data Evaluating Feline Pathogens from Wound and Abscess Samples in the U.S. During 1998<sup>1</sup>**

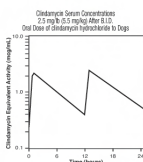
Organism	Number of Isolates	MIC <sub>50</sub>	MIC <sub>90</sub>	Range
<i>Bacteroides/Prevotella</i>	30	0.06	4.0	≤0.015-4.0
<i>Fusobacterium</i> spp.	17	0.25	0.25	≤0.015-0.5
<i>Peptostreptococcus</i> spp.	18	0.13	0.5	≤0.015-8.0
<i>Porphyromonas</i> spp.	13	0.06	0.25	≤0.015-8.0

- The correlation between the *in vitro* susceptibility data and clinical response has not been determined.

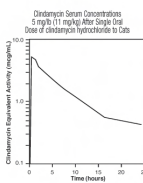
## PHARMACOLOGY

**Absorption:** Clindamycin hydrochloride is rapidly absorbed from the canine and feline gastrointestinal tract.

**Dog Serum Levels:** Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 5.0 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.



**Cat Serum Levels:** Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 5.0 mg/lb of clindamycin hydrochloride every 24 hours. The average peak serum concentration of clindamycin occurs approximately 1 hour after oral dosing. The elimination half-life of clindamycin in feline serum is approximately 7.5 hours. In healthy cats, minimal accumulation occurs after multiple oral doses of clindamycin hydrochloride, and steady-state should be achieved by the third dose.



days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three to four days if no clinical response to therapy is seen.

## Dosage Schedule:

**Clindamycin Hydrochloride Oral Drops,** to provide 5.0 mg/lb, administer 1 mL/5 lbs body weight once every 24 hours; to provide 15.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

## CONTRAINDICATIONS

Clindamycin Hydrochloride Oral Drops is 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

Not for use in humans. Keep out of reach of children. To obtain a Safety Data Sheet(s), contact First Priority, Inc. at (800) 650-4899 or www.prioritycare.com. Keep Clindamycin Hydrochloride Oral Drops 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 Oral Drops occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of Clindamycin Hydrochloride Oral Drops 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 Oral Drops should be used with caution in animals receiving such agents.

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

## ADVERSE REACTIONS

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

To report adverse reactions or a suspected adverse reaction, call 1-800-650-4899.

## ACTIONS

**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 and cats in the United States are presented in Table 1 and Table 2. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the National Committee for Clinical Laboratory Standards (NCCLS).

**Table 1. Clindamycin MIC Values (µg/mL) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. During 1998-99<sup>1</sup>**

Organism	Number of Isolates			Range
	MIC <sub>50</sub>	MIC <sub>95</sub>	MIC <sub>90</sub>	
Soft Tissue/Wound <sup>2</sup>				
<i>Staphylococcus aureus</i>	17	0.5	0.5	0.25-≥4.0
<i>Staphylococcus intermedius</i>	28	0.25	0.5	0.125-≥4.0
<i>Staphylococcus</i> spp.	18	0.5	0.5	0.25-≥4.0
Beta-hemolytic streptococci	46	0.5	0.5	0.25-≥4.0
<i>Streptococcus</i> spp.	11	0.5	≥4.0	0.25-≥4.0

## 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 Oral Drops 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.

## 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 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.

**Cat Data:** The recommended daily therapeutic dose range for clindamycin hydrochloride (Clindamycin Hydrochloride Oral Drops) is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride (Clindamycin Hydrochloride Oral Drops) was tolerated with little evidence of toxicity in domestic shorthair cats when administered orally at 10x the minimum recommended therapeutic daily dose (11 mg/kg; 5 mg/lb) for 15 days, and at doses up to 5x the minimum recommended therapeutic dose for 42 days.

Gastrointestinal tract upset (soft feces to diarrhea) occurred in control and treated cats with emesis occurring at doses 3x or greater than the minimum recommended therapeutic dose (11 mg/kg/day; 5 mg/lb/day). Lymphocytic inflammation of the gallbladder was noted in a greater number of treated cats at the 110 mg/kg/day (50 mg/lb/day) dose level than for control cats. No other effects were noted. Safety in gestating queens or breeding male cats has not been established.

## HOW SUPPLIED

Clindamycin Hydrochloride Oral Drops is available as 20 mL filled in 30 mL bottles (25 mg/mL) supplied in packers containing 12 cartoned bottles with direction labels and calibrated dosing droppers.

## CONTACT INFORMATION

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact First Priority, Inc. at (800) 650-4899 or www.prioritycare.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

## STORAGE

Store at controlled room temperature between 20° to 25° C (68° to 77° F) [see USP].

Rev. 10-22



Manufactured by:  
First Priority, Inc., Elgin, IL 60123  
www.prioritycare.com

Approved by FDA under  
ANADA # 200-398