ADVERSE REACTIONS: SIDE EFFECTS OCCASIONALLY OBSERVED IN EITHER CLINICAL TRIALS OR DURING CLINICAL USE

- Vomiting and diarrhea.
- Hypersensitivity to clindamycin and lincomycin.

CAUTIONS: ClindaMed™ Oral Drops 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.


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

The use of ClindaMed™ Oral Drops occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of ClindaMed™ 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, ClindaMed™ 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

- Vomiting and diarrhea.
- Hypersensitivity to clindamycin and lincomycin.

CAUTIONS: ClindaMed™ Oral Drops 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.


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

The use of ClindaMed™ Oral Drops occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of ClindaMed™ 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, ClindaMed™ 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.

PRECAUTIONS: During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed. See inside for further details.

INDICATIONS (cont.): Cats: Skin infections (wounds and abscesses) due to Staphylococcus aureus, Staphylococcus intermedius, 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. Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Duration: Treatment with ClindaMed™ 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 four or five days if no response to therapy is seen.

DOSAGE SCHEDULE: ClindaMed™ Oral Drops, administer 1-6 mL/10 lbs body weight every 12 hours.

Dogs: Osteomyelitis Oral: 5.0-15.0 mg/kg body weight every 12 hours.

Duration: Treatment with ClindaMed™ 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: ClindaMed™ 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/kg body weight once every 24 hours depending on the severity of the condition.

Duration: Treatment with ClindaMed™ Oral Drops may be continued up to a maximum of 14 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: ClindaMed™ Oral Drops, to provide 5.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

HOW SUPPLIED: ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

ClindaMed™ Oral Drops liquid (for use in dogs and cats) is a palatable formulation intended for oral administration. Each mL of ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

INDICATIONS: ClindaMed™ Oral Drops (for use in dogs and cats) 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 melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Dental infections due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Osteomyelitis due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Cats:
- Skin infections (wounds and abscesses) due to Staphylococcus aureus, Staphylococcus intermedius, Streptococcus spp., Clostridium perfringens and Bacteroides fragilis.
- Oral: 2.5-15.0 mg/lb body weight every 12 hours.

Duration: Treatment with ClindaMed™ 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 to four days if no clinical response to therapy is seen.

DOSAGE SCHEDULE: ClindaMed™ 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/kg body weight once every 24 hours depending on the severity of the condition.

Duration: Treatment with ClindaMed™ Oral Drops may be continued up to a maximum of 14 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: ClindaMed™ Oral Drops, to provide 5.0 mg/lb, administer 3 mL/5 lbs body weight once every 24 hours.

HOW SUPPLIED: ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

ClindaMed™ Oral Drops liquid (for use in dogs and cats) is a palatable formulation intended for oral administration. Each mL of ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

INDICATIONS: ClindaMed™ Oral Drops (for use in dogs and cats) 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 melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Dental infections due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Osteomyelitis due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.
- Cats:
- Skin infections (wounds and abscesses) due to Staphylococcus aureus, Staphylococcus intermedius, Streptococcus spp., Clostridium perfringens and Bacteroides fragilis.
- Oral: 2.5-15.0 mg/lb body weight every 12 hours.

Duration: Treatment with ClindaMed™ 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 to four days if no clinical response to therapy is seen.

DOSAGE SCHEDULE: ClindaMed™ Oral Drops, administer 2-6 mL/10 lbs body weight every 12 hours.
ClindaMed™
(clindamycin)
Oral Drops. Liquid FOR USE IN DOGS AND CATS
ANADA 200-638. Approved by FDA

FOR ANIMAL USE ONLY
KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Equivalent to 25 mg per mL, clindamycin

DESCRIPTION:
ClindaMed™ Oral Drops contain 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.

ClindaMed™ Oral Drops (For Use in Dogs and Cats) is a palatable formulation intended for oral administration. Each mL of ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.84%.

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 2.5 mg/b 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 of clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

ClindaMed Serum Concentrations
2.5 mg/b (0.5 mg/lb) Oral Dose of Clindamycin Hydrochloride Capsules in Dogs

Cat Serum Levels: Serum levels at or above 0.5 μg/mL can be maintained by oral dosing at a rate of 5 mg/b of clindamycin hydrochloride liquid 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.

ClindaMed Serum Concentrations
5 mg/lb (11 mg/kg) After Single Oral Dose of Clindamycin-Hydrochloride Capsules in Cats

PHARMACOKINETICS

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

Distribution:
Clindamycin is widely distributed in body tissues and fluids. Tissue levels are typically about 10% of the serum levels.

Excretion:
Clindamycin is excreted primarily in urine as the inactive metabolites. Small amounts of the active drug are also excreted in urine and feces.

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.

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 toxicology when comparing groups of treated animals with contemporaneous 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 (ClindaMed™ Oral Drops) is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride liquid 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 5X 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.

INDICATIONS:
ClindaMed™ Oral Drops (for use in dogs and cats) 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 intermedium). Deep wounds and abscesses due to Bacteroides fragilis, Prevotella melanogenica, Fusobacterium necrophorum and Clostridium perfringens.

Dental infections due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenica, Fusobacterium necrophorum and Clostridium perfringens.

Osteomyelitis due to Staphylococcus aureus, Bacteroides fragilis, Prevotella melanogenica, Fusobacterium necrophorum and Clostridium perfringens.

Table 1. Clindamycin MIC Values (μg/mL) from Diagnostic Laboratory Survey Data Evaluating Feline Pathogens from Wounds and Abscesses in the U.S. during 1998-99

<table>
<thead>
<tr>
<th>Organism</th>
<th>Number of Isolates</th>
<th>MIC50</th>
<th>MIC90</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteroides spp.</td>
<td>30</td>
<td>0.06</td>
<td>4.0</td>
<td>0.015-4.0</td>
</tr>
<tr>
<td>Proteus spp.</td>
<td>17</td>
<td>0.25</td>
<td>0.25</td>
<td>0.015-0.55</td>
</tr>
<tr>
<td>Peptostreptococcus spp.</td>
<td>18</td>
<td>0.13</td>
<td>0.5</td>
<td>0.015-8.0</td>
</tr>
<tr>
<td>Porphyromonas spp.</td>
<td>13</td>
<td>0.06</td>
<td>0.25</td>
<td>0.015-8.0</td>
</tr>
</tbody>
</table>

1. The correlation between in vitro susceptibility data and clinical response has not been determined.

Table 2. Clindamycin MIC Values (μg/mL) from Diagnostic Laboratory Survey Data Evaluating Feline Pathogens from Wounds and Abscesses Samples in the U.S. during 1998

<table>
<thead>
<tr>
<th>Organism</th>
<th>Number of Isolates</th>
<th>MIC50</th>
<th>MIC90</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteroides spp.</td>
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<td>0.06</td>
<td>4.0</td>
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</tr>
<tr>
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<td>0.25</td>
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</tr>
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<td>0.5</td>
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</tr>
<tr>
<td>Porphyromonas spp.</td>
<td>13</td>
<td>0.06</td>
<td>0.25</td>
<td>0.015-8.0</td>
</tr>
</tbody>
</table>

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ClindaMed™

(•clindamycin)

Oral Drops LIQUID FOR USE IN DOGS AND CATS

ANADA 200-638, Approved by FDA

FOR ANIMAL USE ONLY
KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Equivalent to 25 mg per mL clindamycin

DESCRIPTION:
ClindaMed™ Oral Drops contain clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxy group of a naturally produced antibiotic produced by Streptomyces lincolnensis var. lincolnensis.

ClindaMed™ Oral Drops (For Use in Dogs and Cats) is a palatable formulation intended for oral administration. Each mL of ClindaMed™ Oral Drops liquid contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%. 

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

Dog Serum Levels: Serum levels of at above 0.5 μg/mL can be maintained by oral dosing at a rate of 2.5 mg/kg 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 bioavailability accumulation after a regimen of multiple oral doses in healthy dogs.

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

Cat Serum Levels:
Serum levels of at above 0.5 μg/mL can be maintained by oral dosing at a rate of 5 mg/lb of clindamycin hydrochloride liquid 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.

ClindaMed™ Serum Concentrations
5 mg/lb (11 mg/kg) After Single Oral Dose of Clindamycin-Hydrochloride Capsules to Cats

INDICATIONS:
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 bioavailability accumulation after a regimen of multiple oral doses in healthy dogs.

ClindaMed™ Oral Drops for (use in dogs and cats) 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 melanogenicus, Fusobacterium necrophorum and Clostridium perfringens.

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

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 contemporaries 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 (ClindaMed™ Oral Drops) is 11 to 33 mg/kg/day (5 to 15 mg/lb/day) depending on the severity of the condition. Clindamycin hydrochloride liquid 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/day; 5 mg/lb/day) 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.

INDICATIONS:
ClindaMed™ Oral Drops (for use in dogs and cats) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Number of Isolates</th>
<th>MIC&lt;sub&gt;50&lt;/sub&gt;</th>
<th>MIC&lt;sub&gt;90&lt;/sub&gt;</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft Tissue/Wound</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococci</td>
<td>17</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>aureus clinically</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intermedia</td>
<td>28</td>
<td>0.25</td>
<td>0.25</td>
<td>0.125-4.0</td>
</tr>
<tr>
<td>spp.</td>
<td>18</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>Beta-hemolytic</td>
<td>46</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>streptococci spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptococcus</td>
<td>11</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clostridium Brevii</td>
<td>20</td>
<td>0.5</td>
<td>0.5</td>
<td>0.5</td>
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<tr>
<td>aureus</td>
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<td></td>
<td></td>
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<tr>
<td>intermedia</td>
<td>15</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>spp.</td>
<td>18</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>Beta-hemolytic</td>
<td>21</td>
<td>0.5</td>
<td>2.0</td>
<td>2.0</td>
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<tr>
<td>streptococci spp.</td>
<td>21</td>
<td>0.5</td>
<td>4.0</td>
<td>0.25-4.0</td>
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<tr>
<td>Dermatophilus</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>urealyticdii</td>
<td>25</td>
<td>0.5</td>
<td>4.0</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>intermedia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>spp.</td>
<td>48</td>
<td>0.5</td>
<td>4.0</td>
<td>0.125-4.0</td>
</tr>
<tr>
<td>Beta-hemolytic</td>
<td>32</td>
<td>0.5</td>
<td>4.0</td>
<td>0.25-4.0</td>
</tr>
<tr>
<td>streptococci spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beta-hemolytic</td>
<td>17</td>
<td>0.5</td>
<td>0.5</td>
<td>0.25-0.5</td>
</tr>
</tbody>
</table>

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

1 Soft Tissue/Wound. Includes samples labeled wound, abscess, septic, osteitis, draining tract, lesion, and mass.
2 Dermatophilus Urealyticdii. Includes samples labeled bone, fracture, joint, tendon.
3 No range, all isolates yielded the same value.
4 Oral/dose/units. Includes samples labeled oral, skin, mouth, incision, lip.
5 ClindaMed™ Oral Drops (For Use in Dogs and Cats) contains clindamycin hydrochloride equivalent to 25 mg clindamycin; and ethyl alcohol, 8.64%.

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

<table>
<thead>
<tr>
<th>Organism</th>
<th>Number of Isolates</th>
<th>MIC&lt;sub&gt;50&lt;/sub&gt;</th>
<th>MIC&lt;sub&gt;90&lt;/sub&gt;</th>
<th>Range</th>
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<td>0.06</td>
<td>4.0</td>
<td>≥0.015-4.0</td>
</tr>
<tr>
<td>Prevotella spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fusobacteroids</td>
<td>17</td>
<td>0.25</td>
<td>0.25</td>
<td>≥0.015-0.5</td>
</tr>
<tr>
<td>Peptostreptococcus</td>
<td>18</td>
<td>0.13</td>
<td>0.5</td>
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</tr>
<tr>
<td>Porphyromonon.sp.</td>
<td>13</td>
<td>0.06</td>
<td>0.25</td>
<td>≥0.015-8.0</td>
</tr>
</tbody>
</table>

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2 Dermatophilus Urealyticdii. Includes samples labeled bone, fracture, joint, tendon.
3 No range, all isolates yielded the same value.
4 Oral/dose/units. Includes samples labeled oral, skin, mouth, incision, lip.

The Committee for Clinical Laboratory Standards (NCCLS).
**INDICATIONS** (cont.):

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

Dental infections due to *Staphylococcus aureus*, *Streptococcus intermedius*, *Streptococcus spp.*, *Clostridium perfringens* and *Bacteroides fragilis*.

**CONTRAINDICATIONS:**

ClindaMed™ Oral Drops 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.

**HUMAN WARNINGS:**


**PRECAUTIONS:**

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

The use of ClindaMed™ Oral Drops occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of ClindaMed™ 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, ClindaMed™ 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 1-888-524-6332.