

**FREEDOM OF INFORMATION SUMMARY**

**ANTIROBE Capsules  
(clindamycin hydrochloride)**

**Supplemental NADA 120-161  
Pharmacia & Upjohn Co.**

**Addition of a Dose Range for Dogs  
Addition of a 300 mg Capsule  
Addition of Recent MIC Data**

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## 1. GENERAL INFORMATION

- a. *File Number:* NADA 120-161
- b. *Sponsor:* Pharmacia & Upjohn Co.  
7000 Portage Road  
Kalamazoo, MI 49001-0199 Drug  
Labeler Code: 000009
- c. *Established Name:* clindamycin hydrochloride
- d. *Proprietary Name:* ANTIROBE Capsules
- e. *Dosage Form:* capsules
- f. *How Supplied:* The product is available as follows:  
  
25 mg – bottles of 600  
75 mg – bottles of 200  
150 mg – bottles of 100  
150 mg – blister packages of 100  
300 mg – blister packages of 100 (new)
- g. *How Dispensed:* Prescription (Rx) – US Federal law restricts this drug to use by, or on the order of, a licensed veterinarian.
- h. *Amount of Active Ingredients:* Each capsule (4 strengths) contains the equivalent of 25, 75, 150, and 300 mg of clindamycin hydrochloride
- i. *Route of Administration:* oral
- j. *Species/Class:* dogs
- k. *Recommended Dosage:* The drug is administered at a dose range of 2.5-15 mg/lb every 12 hours for skin infections

(wounds and abscesses), deep wounds and abscesses, and dental infections for a maximum of 28 days. The drug is also administered at a dose range of 5.0-15 mg/lb every 12 hours for osteomyelitis for a minimum of 28 days.

l. *Pharmacological Category:*

antibiotic

m. *Indications:*

ANTIROBE Capsules (brand of clindamycin hydrochloride) are indicated for the treatment of infections in dogs caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

**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*.

n. *Effect of Supplement:*

The supplement provides for the use of clindamycin hydrochloride (ANTIROBE Capsules) in dogs at a dose range of 2.5-15 mg/lb body weight every 12 hours for skin infections (wounds and abscesses), deep wounds and abscesses, and dental infections. It also provides for a dose range in dogs of 5-15 mg/lb every 12 hours for osteomyelitis. In addition, this supplement provides for the addition of a 300 mg capsule. This supplement also provides for the addition of recent MIC data derived from U.S. diagnostic laboratories.

## **2. EFFECTIVENESS**

Please refer to the Freedom of Information (FOI) Summaries for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984 and November 16, 1989. This approval does not affect this section of these summaries, however, a review of this data supports the lower ends of the two dose ranges of 2.5-15 mg/lb and 5-15mg/lb body weight every 12 hours in dogs.

## **3. TARGET ANIMAL SAFETY**

Please refer to the Freedom of Information (FOI) Summary for ANTIROBE Capsules (clindamycin hydrochloride), NADA 120-161, dated June 6, 1984. This approval does not affect this section of the summary, however, a review of this data supports the upper end of the two dose ranges of 2.5-15 mg/lb and 5-15 mg/lb body weight every 12 hours for up to a maximum of 28 days in dogs.

## **4. HUMAN SAFETY**

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "WARNING: Keep out of reach of children. Not for human use."

## **5. AGENCY CONCLUSIONS**

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 514 of the implementing regulations. The data demonstrates that ANTIROBE Capsules (clindamycin hydrochloride), when administered to dogs, are safe and effective when used under labeled conditions.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is judged to be critical in the diagnosis of bacterial infections in animals, treatment of these conditions, and monitoring for possible adverse effects of the drug.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for non-food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

## **6. APPROVED PRODUCT LABELING**

Facsimile Labeling is attached as indicated below:

Package insert

Bottle labels (25 mg, 75 mg, 150 mg)

Blister package labels (150 mg, 300 mg)

Blister package box labels (150 mg, 300 mg)