

SUPPLEMENTAL FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

- A. NADA Number: 048-271
- B. Sponsor: Boehringer Ingelheim Vetmedica, Inc.
15th & Oak
PO Box 339
Elwood, Kansas 66024
- C. Generic Name: Dichlorvos
- D. Trade Name: TASK® Tabs 2, TASK® Tabs 5, TASK® Tabs 10 and
TASK® Tabs 20
- E. Marketing Status: A prescription (Rx) drug that includes the caution
statement as follows:

Federal Law restricts this drug to use by or on the order
of a licensed veterinarian.
- F. Effect of Supplement: 1) To provide for the use of Task® Tabs in kittens not
less than three months of age and in adult dogs.

2) To add two additional tablet sizes, TASK® Tabs 10
and TASK® Tabs 20.

2. INDICATIONS FOR USE

TASK Tabs (dichlorvos) is an anthelmintic product recommended for the removal and control of the roundworms (*Toxocara canis*, *Toxocara cati*, *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma tubaeforme*, *Uncinaria stenocephala*) occurring in the intestinal tract of dogs, puppies, cats and kittens. The drug is vermifugal.

3. DOSAGE FORM, ROUTE OF ADMINISTRATION, RECOMMENDED DOSE

- Dosage Form: Tablet
Route of Administration: Oral

Recommended Dosage: TASK® Tabs are administered as a single dose to provide 5 mg dichlorvos per pound body weight to dogs, puppies, cats and kittens.

4. AND 5. EFFECTIVENESS AND SAFETY

The original NADA was approved May 30, 1973 Federal Register (38 FR 14166), prior to the requirement for preparation of a Freedom of Information Summary.

The data in the original approval were reevaluated to determine the safety and effectiveness of TASK® Tabs in kittens three to five months of age and adult dogs.

Clinical Study 1 in Dogs :

Investigator:

Dr. M. L. Sharp
Sharp Veterinary Research Hospital
Vernon, Texas

General Design:

- (1) Purpose of Study: The purpose of this study was to make an assessment of the effectiveness and safety of Task® Tabs at the doses of 5 and 10 mg/lb of body weight in adult dogs (one to seven years old) and geriatric dogs (over seven years old).
- (2) Test Animals: This study included 15 dogs over 60 pounds. Five geriatric dogs (over 7 years of age) were included in the study. Ten adult dogs (between 1 and 7 years of age) were included in the study. Two dogs in this study had roundworms. All of the dogs had hookworms.

Ten of the dogs were administered 250 mg once. This dose approximated 1X. Three of the dogs were administered two doses of 250 mg (given morning and evening). This dose approximated 2X. Two of the dogs were administered 500 mg once. This dose approximated 5X.

- (3) Results:

The drug was 100 % effective in removing both nematodes. Effectiveness was based on reductions in egg per gram (epg) counts. There were no adverse reactions in noted in this study.

Conclusions:

The study demonstrated the effectiveness and safety of Task® Tabs in adult and geriatric dogs when administered at doses up to 5X.

Clinical Study 2 in Dogs:

Investigators: The fourteen investigators listed below generated data in adult dogs up to 50 lbs.

Dr. R. Billings
Michigan Road Animal Hospital
7720 Michigan Road
Indianapolis, Indiana 46368

Dr. D. G. Carlson
Carson Pet Hospital
311 West Sunshine
Springfield, Missouri 65804

Dr. C. Cullen
730 S. Front Street
Mankato, Minnesota 56001

Dr. E. P. Davis
515 Clifton Terrace
Carrollton, Georgia 30117

Dr. R. H. De Motte
Oden Veterinary Clinic
Highway 58 West
Oden, Kansas 47562

Dr. R. J. Dogue
429 North Maize Road
Wichita, Kansas 67212

Dr. J. S. Elder
Belmont Veterinary Clinic
2900 Belmont Avenue
Youngstown, Ohio 44505

Dr. K. S. Grady
9211 Winston Road
Cincinnati, Ohio 45231

Dr. A. D. Kaplan
Arlington Veterinary Medical Center
71 Massachusetts Avenue
Arlington, Massachusetts 02174

Dr. Kipper
Bloomington Veterinary Hospital
P.O. Box 1480
Bloomington, Indiana

Dr. C. B. Legget
2921 South West Parkway
Wichita Falls, Texas

Dr. L. E. Martin III
1411 North Olive Avenue
Turlock, California 95380

Dr. S. L. Suarvari
1701 Guintoli Lane
Arcata, California 95521

Dr. J. W. Walson
5816 Highway 15 South
Southaven, Mississippi 38671

General Design:

- (1) Purpose of Study: The purpose of this study was to make an assessment of the effectiveness and safety of TASK® Tabs at the dose of 5 mg per pound body weight in adult dogs.
- (2) Test Animals: The study included 171 dogs of various ages, sex, sizes and breeds. The majority of the dogs in the study were adult dogs (between 1 and 7 years old), weighing up to 50 pounds.

- (3) Measurements and Observations: To evaluate effectiveness, eggs per gram (epg) reduction rates and parasite clearance rates were determined. The parasite clearance rate was based upon the number of dogs actually cleared of parasites (egg counts to zero). Fecal counts were conducted both pre-treatment and post-treatment.

Results:

In this study, 171 dogs were treated for roundworm infections and 124 dogs were treated for hookworm infections.

SUMMARY OF CANINE FIELD STUDY - ROUNDWORMS AND HOOKWORMS

Parasite	Clearance Rate	EPG Reduction Rate
Roundworms (ascarids)	157/171 (91.2%)	549 to 17 (96.9%)
Hookworms	114/124 (91.9%)	348 to 16 (95.4%)

The adverse reactions recorded in the clinical trial were related to the cholinergic effects of the drug. The most common adverse reactions recorded were vomiting, excessive salivation, pupillary contraction, dyspnea, watery diarrhea, muscle fasciculations, abdominal pain, ataxia, and general weakness.

Conclusions:

The clinical field study demonstrated the effectiveness and safety of Task® Tabs in adult dogs when administered at a dose of 5 mg/lb of body weight.

Critical Study in Dogs:

Investigator:

D. K. Hass
Shell Chemical Company
San Ramon, California

General Design:

- (1) Purpose of Study: A critical test was conducted to evaluate the effectiveness of TASK® Tabs at the dose of 5 mg per pound body weight in young adult dogs.
- (2) Test Animals: The study included 25 young adult Beagle dogs.
- (3) Measurements and Observations: To evaluate effectiveness, feces were collected for 3 days after treatment and on the fourth day, the dogs were killed and a necropsy

conducted for the purpose of collecting any remaining parasites in the gastrointestinal tract. The necropsy collections and fecal washings were then inspected for the recovery of all parasite populations, and the parasites were identified, counted and tabulated.

Results:

ROUNDWORMS AND HOOKWORMS EXPELLED

Parasite	Number Expelled	% Expelled
<i>Toxocara canis</i>	141/141	100%
<i>Toxascaris leonina</i>	213/292	73%
<i>Ancylostoma caninum</i>	147/151	97.4%

Conclusions:

The study demonstrated the effectiveness of TASK® Tabs for removal and control of roundworms and hookworms in adult dogs.

Clinical Study in Kittens (three to five months of age)

Investigators: Twelve clinical investigators participated in the clinical study.

The investigators were:

Dr. R. E. Billings
 Michigan Road Animal Hospital
 7720 North Michigan Road
 Indianapolis, Indiana 46368

Dr. D. G. Carlson
 Carson Pet Hospital
 311 West Sunshine
 Springfield, Missouri 65804

Dr. C. Cullen
 730 S. Front Street
 Mankato, Minnesota 56001

Dr. R. J. Dogue
429 North Maize Road
Wichita, Kansas 67212

Dr. J. S. Elder
Belmont Veterinary Clinic
2900 Belmont Avenue
Youngstown, Ohio 44505

Dr. K. S. Grady
9211 Winston Road
Cincinnati, Ohio 45231

Dr. A. D. Kaplan
Arlington Veterinary Medical Center
71 Massachusetts Avenue
Arlington, Massachusetts 02174

Dr. Kipper
Bloomington Veterinary Hospital
P.O. Box 1480
Bloomington, Indiana

Dr. C. B. Legget
2921 South West Parkway
Wichita Falls, Texas

Dr. L. E. Martin III
1411 North Olive Avenue
Turlock, California 95380

Dr. S. L. Suarvari
1701 Guintoli Lane
Arcata, California 95521

Dr. J. W. Walson
5816 Highway 15 South
Southaven, Mississippi 38671

General Design:

- (1) Purpose of the study: The purpose of the study was to make an assessment of the effectiveness and safety of Task® Tabs at the dose of 5 mg/lb of body weight in kittens.
- (2) Test Animals: Forty-three kittens 3 to 5 months of age.
- (3) Measurements and Observations: To evaluate the effectiveness, egg per gram (epg) reduction rates and parasite clearance rates were determined. The parasite clearance rate was based on the number of kittens actually cleared of parasites (egg counts to zero). Fecal counts were done both pre-treatment and post-treatment.

Results:

SUMMARY OF FIELD STUDY IN KITTENS-ROUNDWORMS AND HOOKWORMS

Parasite	Clearance Rate	EPG Reduction Rate
Roundworms (ascarids)	91 %	95 %
Hookworms	91 %	94 %

Typical signs of cholinesterase inhibition were observed in the study, but all the kittens recovered with no additional treatment.

Conclusions:

The study demonstrated the effectiveness and safety of Task® Tabs in kittens three to five months of age when administered at a dose of 5 mg/lb.

6. HUMAN FOOD SAFETY

Data on human safety pertaining to consumption of drug residues were not required for this supplemental NADA. The drug is to be labeled for use in dogs, puppies, cats and kittens, which are non-food animals.

7. AGENCY CONCLUSIONS

No new safety or effectiveness data were required to support this supplemental NADA. The data in the original approval were adequate to satisfy the requirements of Section 512 of the Act and Section 514 of the Implementing Regulations. The data demonstrate that Task® Tabs, when used under the labeled conditions of use, are safe and effective.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. This supplement provides for additional tablet sizes and additional claims. Therefore, safety and effectiveness data from the original approval were reevaluated.

Task® Tabs are restricted to use by or on the order of a licensed veterinarian because professional expertise, especially the determination of the specific species of nematodes present, is required to make an accurate diagnosis. In addition, a veterinarian's professional expertise is needed to determine if retreatment is necessary and to determine the importance of any adverse effects.

Attachments:

Labeling:
Package insert
Immediate container label