

Date of Approval: SEP 15 2004

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-265

Prazi-C Tablets
(praziquantel)
34 mg/tablet

OTC Cestocide for use in Dogs and Puppies

For the removal of the *Dipylidium caninum* and *Taenia pisiformis*.

Sponsored by:
Phoenix Scientific, Inc.

200-265

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-265
- b. Sponsor: Phoenix Scientific, Inc.
3915 South 48th St. Terrace
St. Joseph, MO 64503
- Drug Labeler Code: 059130
- c. Established Name: Praziquantel
- d. Proprietary Name: Prazi-C Tablets
- e. Dosage Form: Tablets
- f. How Supplied: 5, 10, or 50 tablets in HDPE bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 34 mg of praziquantel per tablet
- i. Route of Administration: Oral
- j. Species/Class: Dogs and puppies
- k. Recommended Dosage: Tablets may be administered directly per os or crumbled and mixed with feed:

5 lbs. & under	0.5 tablet
6-10 lbs.	1 tablet
11-15 lbs.	1.5 tablets
16-30 lbs.	2 tablets
31-45 lbs.	3 tablets
46-60 lbs.	4 tablets
Over 60 lbs.	5 tablets max

Not intended for use in puppies less than 4 weeks of age. FASTING IS NEITHER NECESSARY NOR RECOMMENDED.

- l. Pharmacological Category: Anthelmintic (cestocide)

- m. Indications: For the removal of *Dipylidium caninum* and *Taenia pisiformis*.
- n. Pioneer Product: TAPE WORM TABS; praziquantel; NADA 111-798; Bayer HealthCare LLC, Animal Health Division
- o. Effect of Supplement: This supplement provides for OTC marketing of Prazi-C (praziquantel) Tablets in 5, 10, and 50-tablet container sizes for use in the removal of the tapeworms, *Dipylidium caninum* and *Taenia pisiformis*, from dogs and puppies. The OTC pioneer product is marketed in 5-tablet container sizes only. The prescription praziquantel product includes additional labeling claims for use by or on the order of a licensed veterinarian, for removal of the canine cestode *Echinococcus granulosus*, and for removal and control of the canine cestode *Echinococcus multilocularis*.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

To show that this generic product is safe and effective for its intended use, an *in vivo* blood level bioequivalence study was conducted. The study objective to determine the bioequivalence of generic and pioneer praziquantel tablets by serum bioequivalence was achieved. Refer to the original FOI Summary dated August 28, 2003, for more detail.

3. HUMAN SAFETY:

This drug is indicated for use only in dogs and puppies, which are non-food animals. Since this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human warning statements are provided on the product labeling as follows: **“Keep out of the reach of children. Not for human use.”**

4. AGENCY CONCLUSIONS:

This ANADA filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Prazi-C Tablets, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-265:

Prazi-C Tabs (praziquantel)

1 – 5 tablet container and carton label; 1 – 10 tablet container label and carton label; 1 – 50 tablet container label and carton label; 1 – package insert

Pioneer Labeling for NADA 111-798:

TAPE WORM TABS (praziquantel)

1 – 5 tablet container label and display card label (inside and outside); 1 – display carton designed to hold 6 containers (front, side and back, top)

For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*
*Not intended for use in puppies less than 4 weeks of age

801004

Iss. 7-02



NDC 59130-762-76

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA

NET CONTENTS: 5 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS 34 mg praziquantel.

Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*

*Not intended for use in puppies less than 4 weeks of age.

801004

Iss. 7-02



NDC 59130-762-76

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA

NET CONTENTS: 5 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS: 34 mg praziquantel.

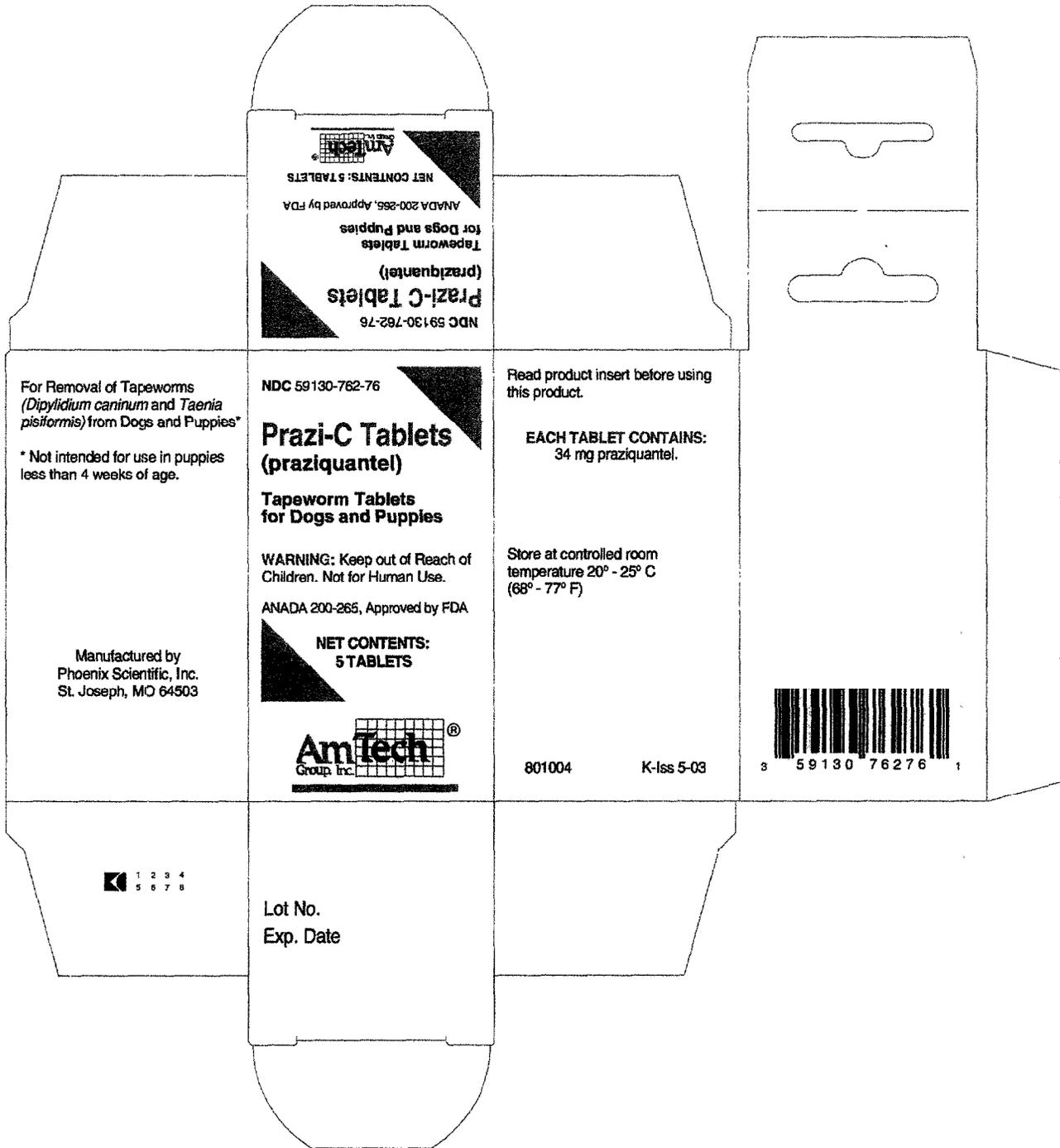
Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

200%



For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*
*Not intended for use in puppies less than 4 weeks of age.

801004

Iss. 2-03



3 59130 76242 6

NDC 59130-762-42

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA

NET CONTENTS: 10 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS: 34 mg praziquantel.

Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*

*Not intended for use in puppies less than 4 weeks of age.

801004

Iss. 2-03



3 59130 76242 6

NDC 59130-762-42

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA

NET CONTENTS: 10 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS: 34 mg praziquantel.

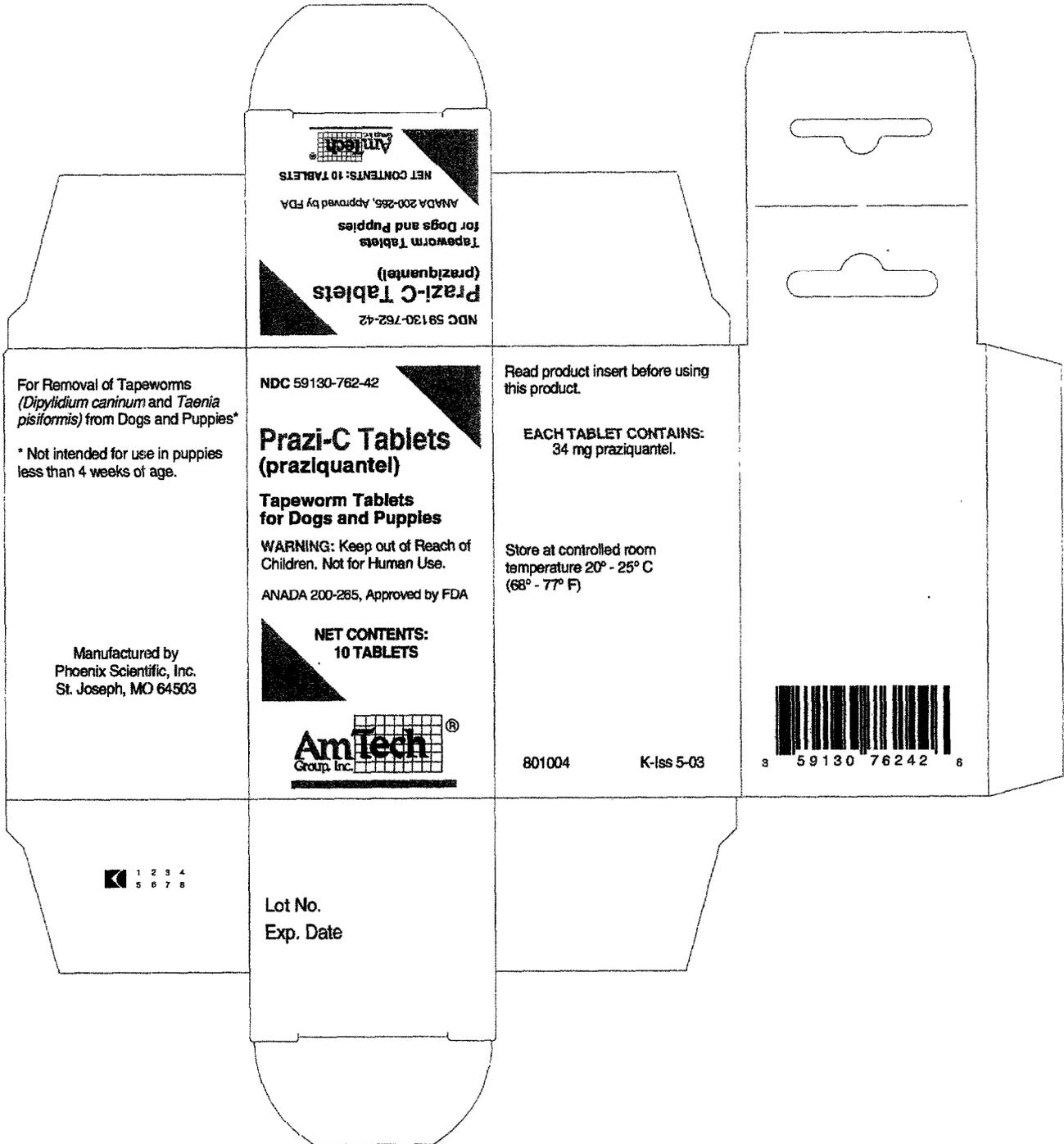
Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

200%



AmTech
 NET CONTENTS: 10 TABLETS
 ANADA 200-265, Approved by FDA
 Tapeworm Tablets
 for Dogs and Puppies
 (praziquantel)
 Prazi-C Tablets
 NDC 59130-762-42

For Removal of Tapeworms
 (*Dipylidium caninum* and *Taenia
 pisiformis*) from Dogs and Puppies*

* Not intended for use in puppies
 less than 4 weeks of age.

NDC 59130-762-42

**Prazi-C Tablets
 (praziquantel)**

**Tapeworm Tablets
 for Dogs and Puppies**

WARNING: Keep out of Reach of
 Children. Not for Human Use.

ANADA 200-265, Approved by FDA

Read product insert before using
 this product.

EACH TABLET CONTAINS:
 34 mg praziquantel.

Store at controlled room
 temperature 20° - 25° C
 (68° - 77° F)

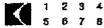
Manufactured by
 Phoenix Scientific, Inc.
 St. Joseph, MO 64503

NET CONTENTS:
 10 TABLETS



801004

K-Iss 5-03



Lot No.
 Exp. Date

For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*
*Not intended for use in puppies less than 4 weeks of age.

801004

Iss. 2-03



NDC 59130-762-15

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA
NET CONTENTS: 50 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS: 34 mg praziquantel.

Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.*

*Not intended for use in puppies less than 4 weeks of age.

801004

Iss. 2-03



NDC 59130-762-15

Prazi-C Tablets (praziquantel)

Tapeworm Tablets for Dogs & Puppies

WARNING: Keep out of Reach of Children.
Not for Human Use.

ANADA 200-265, Approved by FDA
NET CONTENTS: 50 Tablets



Read product insert before using this product.

EACH TABLET CONTAINS: 34 mg praziquantel.

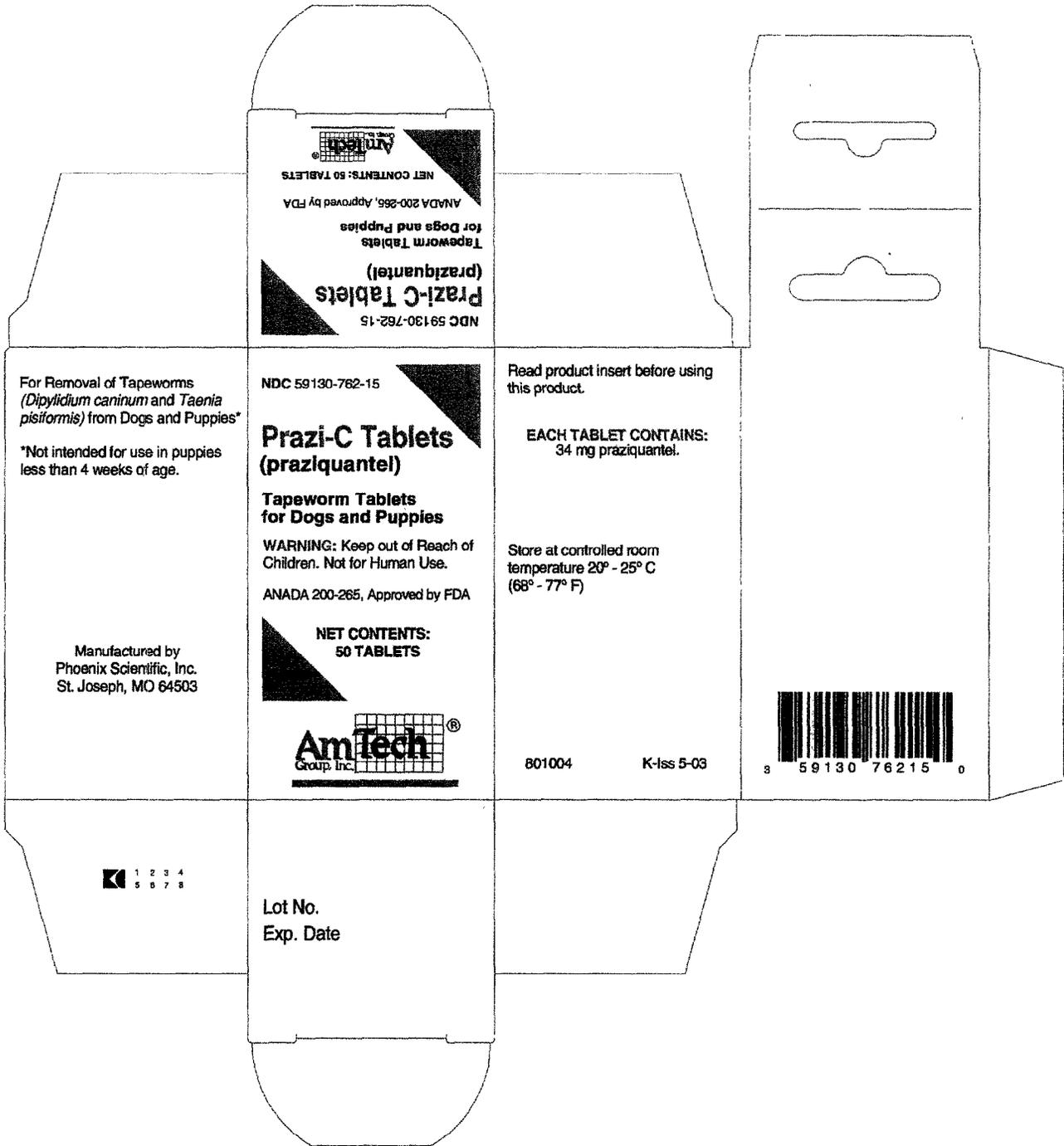
Store at controlled room temperature 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

Lot No.

Exp. Date

200%



ANADA 200-265, Approved by FDA

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Prazi-C Tablets

PRAZIQUANTEL

TAPEWORM TABLETS FOR DOGS AND PUPPIES

Each Tablet Contains 34 mg Praziquantel.

DESCRIPTION: Prazi-C (praziquantel) Tapeworm Tablets for Dogs and Puppies are sized for easy oral administration to either adult dogs or puppies. The tablets may be given directly in the mouth or crumbled and mixed with the food. If given with food, mix the tablet(s) with a small amount of the animal's usual ration. If all of the tablet(s) is/are not eaten, Prazi-C Tapeworm Tablets may not remove all tapeworms.

USES: Prazi-C (praziquantel) Tapeworm Tablets will remove the common tapeworms, *Dipylidium caninum* and *Taenia pisiformis*, from dogs and puppies.

DIRECTIONS FOR USE

Tapeworm infection is one of the most common internal parasite problems actually observed by dog owners. The presence of tapeworms is indicated by the presence of tapeworm segments passed with the feces. Tapeworm segments are white, pinkish-white or yellow-white and similar in size and shape to flattened grains of rice. The segments are most frequently observed lying on the animal's droppings or, less often, moving across a freshly passed stool. Segments are also found on the hair around the anus of the animal, or occasionally on the animal's bedding. Dogs become infected with tapeworms after eating fleas or small mammals (rabbits, hares) which are infected with tapeworm larvae. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

DOSAGE AND ADMINISTRATION: Administer to dogs and puppies* only as follows:

5 pounds and under . . . 1/2 tablet	31-45 pounds 3 tablets
6-10 pounds 1 tablet	46-60 pounds 4 tablets
11-15 pounds 1 1/2 tablets	Over 60 pounds . . . 5 tablets maximum
16-30 pounds 2 tablets	

*Not intended for use in puppies less than 4 weeks of age.

FASTING IS NEITHER NECESSARY NOR RECOMMENDED

RETREATMENT: Steps should be taken to control fleas and small mammals on the premises in order to prevent reinfection; otherwise, retreatment will be necessary. This is especially true in cases of tapeworms transmitted by fleas (*Dipylidium caninum*) where reinfection is almost certain to occur if fleas are not removed from the animal and its environment. If reinfection occurs, tapeworm segments may be observed within one month of the initial treatment.

SIDE EFFECTS: Isolated incidents of either vomiting, diarrhea, poor appetite, or listlessness have been reported following treatment, but were considered non-significant. If these signs are observed and they persist, consult your veterinarian.

WARNING: Consult your veterinarian before administering tablets to weak or debilitated animals.

WARNING: Keep out of the reach of children. Not for human use.

Store at controlled room temperature, 20°-25°C (68°-77°F)

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

801004

Iss. 7-02

Pioneer

Unit Label
Tape Worm Tabs™ (praziquantel)
34 mg Tablets

Lot: **SAMPLE**

**TAPEWORM TABLETS
FOR DOGS AND PUPPIES
WORKING**

**KEEP OUT OF REACH
OF CHILDREN
NOT FOR HUMAN USE**



**TAPEWORM
TABS**

PRAZIQUANTEL

CONTENTS: 6 TABLETS



Mfg. for TradeWinds, Inc.,
St. Joseph, MO USA

Each Tablet Contains 34 mg
praziquantel

For Removal of Tapeworms
(*Theridion caninum* and *Taenia
parvella*) from Dogs and Puppies.

**READ PRODUCT DISPLAY CARD
BEFORE USING THIS PRODUCT**

71906590, P.O. 0656

Pioneer
Card Label - Inside

Unit Carton
(Praziquantel)
34 mg Tablets

TAPE WORM TABS™

PRAZIQUANTEL

TAPEWORM TABLETS FOR DOGS AND PUPPIES

Each Tablet Contains 34 mg Praziquantel.

DESCRIPTION: Tape Worm Tabs™ (praziquantel) Tapeworm Tablets for Dogs and Puppies are sized for easy oral administration to either adult dogs or puppies. The tablets may be given directly in the mouth or crumbled and mixed with the food. If given with food, mix the tablet(s) with a small amount of the animal's usual ration. If all of the tablet(s) is/are not eaten, Tape Worm Tabs™ Tapeworm Tablets may not remove all tapeworms.

USES: Tape Worm Tabs™ (praziquantel) Tapeworm Tablets will remove the common tapeworms, *Dipylidium caninum* and *Taenia pisiformis*, from dogs and puppies.

DIRECTIONS FOR USE

Tapeworm infection is one of the most common internal parasite problems actually observed by dog owners. The presence of tapeworms is indicated by the presence of tapeworm segments passed with the feces. Tapeworm segments are white, pinkish-white or yellow-white and similar in size and shape to flattened grains of rice. The segments are most frequently observed lying on the animal's droppings or, less often, moving across a freshly passed stool. Segments are also found on the hair around the anus of the animal, or occasionally on the animal's bedding. Dogs become infected with tapeworms after eating fleas or small mammals (rabbits, hares) which are infected with tapeworm larvae. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.



DOSAGE AND ADMINISTRATION: Administer to dogs and puppies* only as follows:

5 pounds and under 1/2 tablet	31-45 pounds 3 tablets
6-10 pounds 1 tablet	46-60 pounds 4 tablets
11-15 pounds 1 1/2 tablets	Over 60 pounds	... 5 tablets maximum
16-30 pounds 2 tablets		

*Not intended for use in puppies less than 4 weeks of age.

FASTING IS NEITHER NECESSARY NOR RECOMMENDED

RETREATMENT: Steps should be taken to control fleas and small mammals on the premises in order to prevent reinfection; otherwise, retreatment will be necessary. This is especially true in cases of tapeworms transmitted by fleas (*Dipylidium caninum*) where reinfection is almost certain to occur if fleas are not removed from the animal and its environment. If reinfection occurs, tapeworm segments may be observed within one month of the initial treatment.

SIDE EFFECTS: Isolated incidents of either vomiting, diarrhea, poor appetite, or listlessness have been reported following treatment, but were considered non-significant. If these signs are observed and they persist, consult your veterinarian.

WARNING: Consult your veterinarian before administering tablets to weak or debilitated animals.

WARNING: Keep out of the reach of children. Not for human use.

TW70034

Pioneer
Card Label - Outside

Unit Carton
Tape Worm Tabs™ (praziquantel)
34 mg Tablets

Exp. Date:
Lot No.:



Manufactured for TradeWinds, Inc.,
St. Joseph, MO USA

TRADE WINDS™

75008560, B.O.
WARNING: Keep out of the reach of children. Not for human use.
Consult your veterinarian before administering tablets to weak or debilitated animals.
If they persist, consult your veterinarian.
SIDE EFFECTS: Isolated incidents of either vomiting, diarrhea, poor appetite, or listlessness have been reported following treatment, but were considered non-significant. If these signs are observed and persist, consult your veterinarian.
Directions for Use: Tapeworm infection is one of the most common internal parasite problems actually observed by dog owners. The presence of tapeworms is indicated by the presence of tapeworm segments passed with the feces. Tapeworm segments are white, pinkish-white or yellow-white and similar in size and shape to flattened grains of rice. The segments are most frequently observed lying on the animal's droppings or less often, moving across a freshly passed stool. Segments are also found on the hair around the anus of the animal, or occasionally on the animal's bedding. Dogs become infected with tapeworms after eating dead or small mammals (rabbits, hares) which are infected with tapeworm larvae. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.
Directions for Use: Tapeworm Tablets will remove the common tapeworms, *Dipylidium caninum* and *Taenia pisiformis*, from dogs and puppies.
0838

TAPE WORM TABS™

PRAZQUANTEL

TAPEWORM TABLETS
FOR DOGS AND PUPPIES



For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.

WARNING
KEEP OUT OF REACH OF CHILDREN
NOT FOR HUMAN USE

Read entire card before using this product.

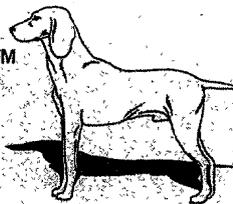
CONTENTS: 5 TABLETS

TRADE WINDS™

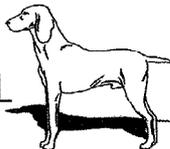
Pioneer
Display Carton - Front

Multi Carton
Tape Worm Tabs™ (praziquantel)
34 mg Tablets

TAPE WORM TABS™
PRAZIQUANTEL



**TAPE WORM
TABS™**
PRAZIQUANTEL
TAPEWORM TABLETS
FOR DOGS AND PUPPIES



For Removal of Tapeworms (*Dipylidium caninum* and *Taenia pisiformis*) from Dogs and Puppies.

WARNING
KEEP OUT OF REACH OF CHILDREN
NOT FOR HUMAN USE

**READ PRODUCT DISPLAY CARD
BEFORE USING THIS PRODUCT.**

CONTENTS: 6 BOTTLES – 5 TABLETS EACH 0656
Each Tablet Contains 34 mg Praziquantel. 77006560, R.O

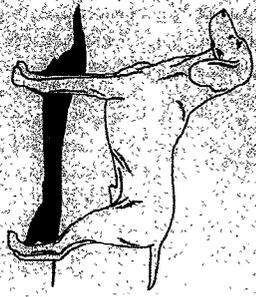


Manufactured for TradeWinds, Inc.,
St. Joseph, MO USA

Pioneer
Display Carton - Side & Back

Pioneer
Display Curtain - Top

**TAPE WORM
TABS™**
PRAZIQUANTEL
TAPEWORM TABLETS
FOR DOGS AND PUPPIES



TRADE WINDS™

