

FREEDOM OF INFORMATION SUMMARY

**ZODIAC® FLEATROL™ FLEA CAPS™
HARTZ® FLEA CONTROL CAPSULES™
NADA 141-162**

“for use in dogs, nine weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-Methoprene prevents and controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.”

Sponsored by:

**Wellmark International
1000 Tower Lane
Bensenville, IL 60106**

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I. GENERAL INFORMATION:

NADA Number: NADA 141-162

Sponsor: Wellmark International
1000 Tower Lane
Bensenville, IL 60106

Generic Name: (S)-Methoprene

Trade Names: ZODIAC® FLEATROL™ FLEA CAPS™
HARTZ® FLEA CONTROL CAPSULES™

Marketing Status: OTC (Over-the-Counter)

II. INDICATIONS FOR USE:

ZODIAC® FLEATROL™ FLEA CAPS™ and HARTZ® Flea Control Capsules™ are indicated for use in dogs, nine weeks of age and older and 4 pounds body weight or greater, for the prevention and control of flea populations. (S)-Methoprene prevents and controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND DOSAGE:

Dosage Form: capsule

Route of Administration: oral

Dosage and administration: The capsules are given orally once per week at the recommended minimum dosage of 10 mg (S)-Methoprene per pound of body weight (22 mg/kg) according to the following schedule.

Dog Weight	No. of capsule(s) per week	mg (S)-Methoprene per Capsule	Color
4 to 15 lbs.	1 Capsule	154 mg	Green
16 to 30 lbs.	1 Capsule	308 mg	Red
31 to 45 lbs.	1 Capsule	462 mg	Lavender
46 to 60 lbs.	2 Capsules	308 mg	Blue
61 to 90 lbs.	2 Capsules	462 mg	Brown
91 to 135 lbs.	3 Capsules	462 mg	Brown
136 to 180 lbs.	4 Capsules	462 mg	Brown

IV. EFFECTIVENESS:

(S)-Methoprene is an insect growth regulator (IGR) which breaks the flea life cycle at the egg stage. The adult female flea is exposed to the drug when feeding on a treated dog. The drug, which has no deleterious effect on the adult flea, acts to inhibit the development of flea eggs.

A. DOSE DETERMINATION STUDY:

Title: A Dose Titration Study to Determine the Effective Level of Oral (S)-Methoprene in Dogs for the Inhibition of Cat Flea (*Ctenocephalides felis*) Egg Hatch.

Purpose: To determine the effective level of orally administered (S)-Methoprene for the control of the cat flea (*Ctenocephalides felis*) on dogs.

Investigators/Study Locations:

Dr. Michael Lytwyn
Hartz Mountain Corporation
Bloomfield, NJ

Dr. Marvin L. Sharp
Sharp Veterinary Research
Vernon, TX

Animals: 24 mixed breed dogs (12 males and 12 females)
1 year of age and older, 6 kg-28 kg, 6 groups (4 dogs per group)

Dosage Groupings: placebo (excipients without active ingredients)
10 mg/kg (S)-Methoprene
20 mg/kg (S)-Methoprene
25 mg/kg (S)-Methoprene
50 mg/kg (S)-Methoprene
Initial dose of 40 mg/kg followed by 20 mg/kg once a week

Route of Administration: Oral, mixed into 50 grams of canned dog food

Frequency of Treatment: Once per week

Duration of Study: 35 days for egg collection
64 days for adult emergence

Study Design: Starting on day 0, treatments were administered to all animals once per week until day 28. Each dog was infested with 200 fleas throughout the study and flea eggs were collected on days -7, 2, 7, 9, 14, 21, 28 and 35.

Parameters Measured: The cumulative percent reduction in adult flea emergence from eggs deposited on days 2-28 and 2-35.

Results: The following table shows the cumulative percent reduction in adult flea emergence for days 2 through 28 and days 2 through 35.

**CUMULATIVE PERCENT REDUCTION IN ADULT FLEA EMERGENCE
ON DAYS 2-28 AND 2-35**

TREATMENT GROUP	DAYS 2-28	DAYS 2-35
10.0 mg/kg	74.9%	79.3%
20.0 mg/kg	91.8%	93.3%
25.0 mg/kg	99.6%	99.7%
50.0 mg/kg	99.8%	99.9%
40, 20 mg/kg	99.1%	99.1%

Conclusions: (S)-Methoprene administered at 20 mg/kg provided greater than 90% reduction in adult flea emergence on days 2-28 and 2-35 and was selected as the dosage for further testing.

Adverse Reactions: There were no adverse reactions reported.

B. DOSE CONFIRMATION STUDY:

Title: A Study to Confirm the Efficacy of an Oral (S)-Methoprene Capsule in Dogs for the Inhibition of Cat Flea (*Ctenocephalides felis*) Emergence.

Purpose: To confirm the effectiveness of orally administered (S)-Methoprene in a capsule for the Inhibition of Cat Flea (*Ctenocephalides felis*) egg hatch.

Investigators/Study Locations:

Dr. Michael Lytwyn
Hartz Mountain Corporation
Bloomfield, NJ

Dr. Marvin L. Sharp, DVM
Sharp Veterinary Research
Vernon, TX

Animals: 20 mixed breed dogs (10 males, 10 females)
6 months of age or older, 6 kg-28 kg, 2 groups (10 dogs per group)

Dosage Groupings: placebo (excipients without active ingredients)
22 mg/kg (S)-Methoprene

Route of Administration: Oral, capsules (Days 0, 7)
Mixed into 50 grams of canned dog food (Day 14)

Frequency of Treatment: Once weekly prior to feeding on days 0, 7, and 14

Duration of Study: 42 days

Study Design: Each animal was infested with 200 fleas on days -12, 0, 7, and 14. On day 14, five of the dogs in each treatment group were administered whole capsules after being fed, while the remaining five received their treatment mixed with food. Flea eggs were collected on days 2, 7, 9, 14, 16, 21, and 23.

Parameters Measured: The percent reduction in adult flea emergence.

Results: The percent reduction in adult emergence for the (S)-Methoprene treatment group between egg collection days 2 and 14 was 96.1% (See the table below).

% REDUCTION IN ADULT FLEA EMERGENCE

TEST GROUP	TOTAL # OF ADULTS EMERGED/TOTAL # OF EGGS COLLECTED
(S)-Methoprene	37/2379
Placebo	963/2400
Emergence rate*	96.1%

*Emergence rate =

total # of adults emerged/total # of eggs collected (placebo group) - total # of adults emerged/total # of eggs collected (treated group)
total # of adults emerged/total # of eggs collected (placebo group)

Conclusions: (S)-Methoprene administered at 22 mg/kg provided a 96.1% reduction in adult flea emergence.

Adverse Reactions: There were no adverse reactions reported.

C. CLINICAL FIELD TRIAL:

Title: A Clinical Trial to Determine the Efficacy of a Once a Week Oral (S)-Methoprene Capsule for the Control of Cat Flea (*Ctenocephalides felis*) Populations on Dogs.

Purpose: To confirm the effectiveness and safety of (S)-Methoprene for the control of flea populations under field conditions.

Investigators/Study Locations:

Richard Johnson, D.V.M. Broadway Animal Hospital El Cajon, California	Louis Gotthelf, D.V.M. Animal Hospital of Montgomery Montgomery, Alabama
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Investigators/Study Locations (con't):

David Nielsen, D.V.M. Animal Medical Group Manhattan Beach, California	Ted Lamp, D.V.M. Bellville Veterinary Clinic Bellville, Texas
George Bailey, D.V.M. Country Club Animal Hospital Miami, Florida	Chris Jenkins, D.V.M. Creature Comfort Animal Clinic Arlington, Texas
Mark Pelham, D.V.M. Kelley Animal Hospital Birmingham, Alabama	Karen Fling, D.V.M. East Lake Veterinary Hospital Dallas, Texas
Bob Cartin, D.V.M. Mission Animal Hospital Oceanside, California	Michael Shumer, D.V.M. Beach Boulevard Animal Hospital Jacksonville, Florida
Stephen Collier, D.V.M. Parkway Animal Hospital Panama City, Florida	

Animals: A total of 246 (118 males, 127 females) dogs were enrolled in the study (the sex of one animal was not reported). Of these, 165 client owned dogs ranging in age from 6 months to 16 years and weighing between 4 to 130 pounds, were included in the statistical analysis. Sixty-one of the 165 dogs were treated with (S)-Methoprene.

Dosage Groups: positive control (lufenuron tablets: minimum of 10 mg/kg)

minimum of 22 mg/kg (S)-Methoprene

Route of Administration: Oral, lufenuron (in conjunction with or following a meal)
Oral, (S)-Methoprene (by mouth, in a treat or mixed into the food)

Frequency of Treatment: lufenuron: once monthly for five months
(S)-Methoprene: once weekly for five months

Duration of Study: 5 months

Study Design: All dogs enrolled (single and multi-dog households) were harboring natural flea infestations. A burden of at least 20 fleas was required for single dog households and at least one dog in a multi-dog household was required to have at least 20 fleas. Each client received Adams™ Flea and Tick Mist for application once per week for the first eight weeks to eliminate the existing adult flea burdens. The mist was not for use within 5 days before a flea count. Bathing was not permitted within 5 days prior to flea counts and insecticidal shampoos were not allowed. Other treatments and medications commonly used in veterinary practices were allowed.

Parameters Measured: Adult flea counts (months 0, 1, 2, 3, 4, and 5) and percent inhibition of fleas.

Results: Refer to the table below for the geometric mean flea counts and percent inhibition of fleas. The geometric flea counts were used to compute the percent inhibition (PI) of fleas: $PI_t = [(GM_0 - GM_t)/GM_0] \times 100\%$.

GEOMETRIC MEAN FLEA COUNTS AND PERCENT INHIBITION OF FLEAS BY MONTH

Month	GEOMETRIC MEAN FLEA COUNT		PERCENT INHIBITION OF FLEAS	
	Program®	(S)-Methoprene	Program®	(S)-Methoprene
0	74.86	68.18		
1	25.30	18.05	66.2	73.5
2	14.49	8.55	80.6	87.5
3	9.23	9.72	87.7	85.7
4	7.71	6.94	89.7	89.8
5	4.89	4.89	93.5	92.8
1-5	10.75	8.77	85.6	87.1

GM_0 = geometric mean flea count for month 0

GM_t = geometric mean count either for month t (t = 1, 2, 3, 4, or 5) or months 1 to 5 combined.

Conclusions: (S)-Methoprene, administered at a minimum dose of 22 mg/kg body weight at weekly intervals during active flea infestations, effectively controlled the flea populations. (S)-Methoprene, an insect growth regulator (IGR) which has no effect on the adult flea, was used in combination with a topical insecticide to kill the adults for the first 2 months of the study when the pre-existing fleas were at their heaviest. (S)-Methoprene capsules worked as effectively as the positive control.

Adverse Reactions: Vomiting, diarrhea, lethargy/depression and nervousness were observed in the (S)-Methoprene group.

D. LABORATORY SIMULATED HOME ENVIRONMENT TRIAL:

Title: A Study to Determine the Efficacy of a Once a Week Oral (S)-Methoprene Capsule for the Prevention of Cat Flea (*Ctenocephalides felis*) Populations on Dogs.

Purpose: To confirm the effectiveness and safety of (S)-Methoprene for the prevention of flea populations under a laboratory simulated home environment.

Investigator/Study Location: Suzanne Craig, DVM
Stillmeadow Inc.
Sugar Land, TX

Animals: 20 dogs (10 males and 10 females) of various breeds, 8 months to 4 years of age, 14 to 61 pounds body weight

Dosage Groups: negative control (untreated)
22 mg/kg (S)-Methoprene

Route of Administration: oral

Frequency of Treatment: negative control: untreated
(S)-Methoprene: once weekly

Duration of Study: 91 days

Study Design: The dogs were individually housed in cages with partially carpeted runs. Treatment began on day 0 and continued weekly through day 84. Flea populations were established initially by infesting each dog with 100 unfed, adult cat fleas 24 hours after the first treatment (day 1) and maintained by additional infestations on days 5, 8, 12, and 15. The carpeted platform was sprinkled with ground dog food, dried beef blood, and sand on study day 1 to provide a food source for developing fleas.

Parameters Measured: Adult flea counts weekly starting on day 21. Counts were not done the first 2 weeks after treatment to leave the adults undisturbed and to encourage reproduction during the early phases of the study.

Results: (S)-Methoprene capsules demonstrated 93.8% percent reduction of adult fleas by day 49-post treatment. Refer to the table below for the means and percent reductions in adult flea counts.

PERCENT REDUCTION IN ADULT FLEA COUNTS

DAY OF STUDY	CONTROL GEOMETRIC MEANS	(S)-METHOPRENE GEOMETRIC MEANS	PERCENTAGE REDUCTION
21	50.6	42.0	17.0
28	47.2	8.5	82.0
35	56.6	15.8	72.1
42	102.4	17.5	82.9

PERCENT REDUCTION IN ADULT FLEA COUNTS (con't)

DAY OF STUDY	CONTROL GEOMETRIC MEANS	(S)-METHOPRENE GEOMETRIC MEANS	PERCENTAGE REDUCTION
49	123.6	7.7	93.8

56	149.2	7.6	94.9
63	203.1	23.6	88.4
70	218.9	22.7	89.6
77	292.2	23.2	92.1
84	414.9	33.8	91.9
91	499.9	36.5	92.7

Conclusions: (S)-Methoprene capsules administered weekly at 22 mg/kg were effective for the prevention of cat flea (*Ctenocephalides felis*) populations on dogs. There was 93.8% reduction in the adult flea counts by day 49.

Adverse reactions: There were no adverse reactions reported.

V. ANIMAL SAFETY:

A. TARGET ANIMAL SAFETY:

Title: A Target Animal Safety and Tolerance Study of (S)-Methoprene Capsules Administered Orally Once per week to Beagle Dogs.

Purpose: To determine the safety of three dosage levels (1X, 3X and 5X) of (S)-Methoprene following 13 weeks of exposure and to investigate the tolerance effects at 10X for 4 weeks.

Investigator/Study Location: Thomas R. Carpenter, DVM, Ph.D.
Director of Toxicology,
HTI Bio-Services, Inc.,
San Diego, CA

Animals: 32 Beagle puppies (16 males and 16 females), approximately 6-weeks old, 1.62-2.10 kg body weight. Groups 1-4 (6/group) and Groups 5 and 6 (4/group), divided equally by sex

Dosage Groups: Group 1: Negative control (untreated)
Group 2: 1X (22 mg/kg (S)-Methoprene)
Group 3: 3X (66 mg/kg (S)-Methoprene)
Group 4: 5X (110 mg/kg (S)-Methoprene)
Group 5: 10X (220 mg/kg (S)-Methoprene)

Dosage Groups: Group 6: Negative control (untreated)

Route of Administration: orally, followed by a water rinse. The 10X dose was split into two doses, administered within a period of 1 to 2 hours.

Frequency of Treatment: Groups 2, 3 and 4 treated once weekly for 13 weeks
Group 5 treated once weekly for 4 weeks

Duration of Study: 90 days (13 weeks) Groups 1-4
28 days Groups 5 and 6

Parameters Measured: Dogs were observed daily to determine pharmacological and/or toxicological effects. Two physical examinations were performed during the baseline period. Body weights and food consumption were measured weekly. Ophthalmic exams were performed during baseline and the final week of treatment. Blood specimens were collected for hematology, clinical chemistry and coagulation profiles

(day -2, 21 and 56), and on the day of necropsy. Animals were euthanized at study completion and organ weights, gross pathology and histology samples were obtained.

Results: There were no adverse effects on body weight, food consumption, ophthalmology, clinical pathology, urinalyses, organ weights, gross pathology or histology. The clinical signs included depression, ataxia (loss of balance) and tremors.

Depression was exhibited as depicted below. All dogs returned to normal by the following observation (next morning). Two dogs in the 3x treatment group and 1 in the 10x group exhibited depression twice on days 0 and 7. By day 14 only 1 dog exhibited mild depression.

DEPRESSION BY DAY AND TREATMENT GROUP

TREATMENT GROUP	DAY 0	DAY 7	DAY 14
1x	2/6		
3x	3/6	3/6	1/6
5x	1/6	3/6	
10x	1/4	3/4	

Ataxia was exhibited as depicted below. All dogs returned to normal by the following observation.

ATAXIA BY DAY AND TREATMENT GROUP

	DAY 0	DAY 7	DAY 14	DAY 21	DAY 56
1x	2/6				
3x	2/6	4/6	3/6		1/6
5x	5/6	3/6	2/6		
10x	2/4	4/4	2/4	1/4	

Tremors were exhibited in 1/6 and 1/4 dogs in the 1x and 10x treatment groups, respectively on day 0. All dogs returned to normal by the following observation.

Conclusions: (S)-Methoprene capsules caused clinical signs including depression, ataxia and tremors when administered at 1X, 3X, 5X and 10X the recommended dose in 6 week old puppies. (S)-Methoprene caused depression and ataxia when administered at 3X, 5X and 10X the recommended dose in 7 week old puppies; depression when administered at 3X the recommended dose in 8 week old puppies and ataxia when administered at 3X, 5X and 10X the recommended dose in 8 week old puppies. By day 21 of the study, when the puppies were 9 weeks of age, one puppy in the 10X group experienced ataxia.

(S)-Methoprene capsules (22 mg/kg), administered up to 5X the recommended dose, are safe for administration to puppies, 9 weeks of age and older and 4 pounds body weight or greater.

B. REPRODUCTIVE SAFETY:

Title: A Domestic Animal Safety Study (1-Generation Reproduction) of (S)-Methoprene in the Dog via Capsule Administration.

Purpose: To determine the safety of (S)-Methoprene administration in breeding male and female dogs at 3X the recommended dose.

Investigator/Study location: Steve Godin, Ph.D., DABT
Director of Toxicology
White Eagle Toxicology Laboratories, Inc.
Doylestown, PA

Animals: 52 Beagle dogs (20 males and 32 females), approximately 2-8 years of age, 9.7-15.6 kg body weight. Groups 1-2 (10 males and 16 females/group)

Dosage Groups: Group 1: Negative control (untreated)
Group 2: 3X (66 mg/kg (S)-Methoprene)

Route of Administration: orally

Frequency of Treatment: (S)-Methoprene administered weekly through weaning (mated males and 10 females) or up to parturition (unmated males and 6 unmated females)

Duration of Study: approximately 7 months

Study Design: Group 1 (10 males, 16 females) served as the untreated control and received diet only. Group 2 (10 males, 16 females) was administered 3X the recommended dose of (S)-Methoprene weekly for 12 weeks. Following the administration of the test article for 12 weeks, 10 females each from Groups 1 and 2 were mated to 10 males from the same treatment group as they came into estrus. Weekly dosing continued during gestation, parturition and weaning. The 6 unmated females and males in Group 2 were administered (S)-Methoprene at 3X the recommended dose weekly until all of the mated females delivered litters.

Parameters measured:

Adult males and females: Physical examinations prior to mating and at study conclusion. Body weights were measured one week prior to treatment initiation, on the day prior to treatment initiation, and weekly during the study. Observations were made twice daily for pharmacological and/or toxicological effects. Blood specimens were collected for hematology and clinical chemistry at pretest, prior to mating, and at the conclusion of the study.

Pups: Physical examinations within 24 hours of birth and weekly during the 6-week lactation period. Pup weights were recorded within 24 hours after whelping and weekly during the 6-week lactation period. Litters were observed within 24 hours of whelping and twice daily thereafter for pharmacological and/or toxicological effects. The numbers of live and dead pups were recorded weekly starting on day 0 until the end of lactation.

Semen collection and evaluation: Semen was collected and evaluated at pretest and within the female estrous cycle prior to the initiation of mating. The following parameters were recorded: volume, color, motility, total sperm counts, pH, and morphology.

Results: There were no adverse effects on body weight, food consumption, clinical pathology (hematology/serum chemistry) or semen analyses and no reported adult deaths. Nine of 72 pups in Group 1

and 13 of 76 pups in Group 2 died prior to weaning. The puppy deaths in both groups were attributed to other causes (stillborn, maternal neglect, prematurity, peritonitis, and pulmonary edema) and were not considered drug related. One clinical observation was drug related; discolored feces (green), observed in the (S)-Methoprene group, were associated with the gelatin colored capsules administered.

Conclusions: (S)-Methoprene capsules (22 mg/kg), administered up to 3X the recommended dose, are safe for administration to male and female breeding dogs.

C. COMBINATION FLEA ADULTICIDE STUDY

Title: A Study to Determine the Safety of (S)-Methoprene Capsules at 5X the Recommended Dose in Combination with Commercial Flea Adulticides in Beagle Puppies.

Purpose: To determine the safety of (S)-Methoprene administration at 5X the recommended dose in combination with commercial flea adulticides.

Investigator/Study Location: Steve Godin, Ph.D., DABT
Director of Toxicology
White Eagle Toxicology Laboratories, Inc.
Doylestown, PA

Animals: 24 Beagle dogs (12 males and 12 females), approximately 6-10 weeks of age, 2.8-8.6 lbs. body weight. Groups 1-4 (3 males and 3 females/group)

Dosage Groups: Phase I: Group 1: Frontline Top Spot (fipronil)
Group 2: Top Paw shampoo (permethrin/piperonyl butoxide)
Group 3: Derma Dip (phosmet)
Group 4: Zodiac Flea collar (carbaryl)
Phase II: Group 1: Frontline Top Spot and 5X (S)-Methoprene
Group 2: Top Paw shampoo and 5X (S)-Methoprene
Group 3: Derma Dip and 5X (S)-Methoprene
Group 4: Zodiac Flea collar and 5X (S)-Methoprene

Route of Administration: (S)-Methoprene was administered orally and the commercial flea adulticides were applied topically, according to label instructions

Frequency of Treatment: Phase I: Each group received the respective flea adulticide according to label instructions for 2 weeks. A one-week washout period followed Phase I.

Phase II: (S)-Methoprene at a 5X oral dose was administered once weekly for 4 weeks in combination with the flea adulticide.

Duration of Study: 7 weeks

Parameters Measured: Physical examinations were conducted on all animals prior to dosing and at study conclusion. Body weights were measured prior to acclimation, on the day prior to treatment initiation, and weekly during the study. Food consumption was recorded daily starting at acclimation through study completion. Observations were made twice daily for signs of pharmacological and/or toxicological effects. Blood was collected for clinical pathology (hematology/serum chemistry) analyses during phases I and II as illustrated below:

BLOOD COLLECTION DAYS (PHASES I AND II)

Group	PHASE I		Washout Period	PHASE II
	Treatment Type	Clinical Pathology Samples		Clinical Pathology Samples
1	Frontline Top Spot	Days 4 and 9	Days 21-27	Day 50
2	Top Paw	Days 4 and 16	Days 21-27	Day 50
3	Derma-Dip	Days 4 and 16	Days 21-27	Day 50
4	Zodiac Collar	Days 4 and 21	Days 21-27	Day 50

Results: There were no adverse effects on body weight, food consumption, clinical pathology (hematology/serum chemistry) and no reported deaths.

Conclusions: (S)-Methoprene capsules (22 mg/kg), administered up to 5X the recommended dose, are safe for administration in combination with commercially available flea adulticides.

VI. HUMAN SAFETY:

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this NADA. This drug is to be labeled for use in dogs, which are not food animals.

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

VII. AGENCY CONCLUSIONS:

The data in support of this NADA comply with the requirements of Section 512 of the Act and Section 514 of the implementing regulations. The data demonstrate that ZODIAC® FLEATROL™ FLEA CAPS™ and HARTZ® Flea Control Capsules™, when used under the labeled conditions of use, are safe and effective.

Because adequate directions for the safe and effective lay use of ZODIAC® FLEATROL™ FLEA CAPS™ and HARTZ® Flea Control Capsules™ could be written, the products have been labeled for over-the-counter distribution.

Under section 512(c)(2)(F)(i) of the FFDCA, this approval qualifies for FIVE years of marketing exclusivity beginning on the date of approval because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

Wellmark International patent pending in the U.S.

VIII. LABELING (attached)

I. ZODIAC® FLEATROL™ FLEA CAPS™

- A. Package Insert
- B. Carton
- C. Blister Pack

II HARTZ® Flea Control Capsules™

- A. Package Insert
- B. Carton
- C. Blister Pack