

Date of Approval: June 6, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-417

CORAXIS

Moxidectin

Solution

Dogs

CORAXIS (moxidectin) is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*, and for the treatment and control of *Ancylostoma caninum* (adults, immature adults, and fourth stage larvae), *Uncinaria stenocephala* (adults, immature adults, and fourth stage larvae), *Toxocara canis* (adults and fourth stage larvae), *Toxascaris leonina* (adults), and *Trichuris vulpis* (adults) in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 pounds.

Sponsored by:

Bayer HealthCare LLC

Animal Health Division

Table of Contents

I. GENERAL INFORMATION	3
II. EFFECTIVENESS.....	5
A. Dosage Characterization	5
B. Substantial Evidence	5
III. TARGET ANIMAL SAFETY:.....	5
IV. HUMAN FOOD SAFETY:	6
V. USER SAFETY:	6
VI. AGENCY CONCLUSIONS:	6
A. Marketing Status:	6
B. Exclusivity:	7
C. Patent Information:	7

I. GENERAL INFORMATION

A. File Number

NADA 141-417

B. Sponsor

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, KS 66201

Drug Labeler Code: 000859

C. Proprietary Name

CORAXIS

D. Established Name

Moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Solution

G. Amount of Active Ingredient

2.5% moxidectin

H. How Supplied

Applications per Package:
6 x 0.4 ml tubes
6 x 1.0 ml tubes
6 x 2.5 ml tubes
6 x 4.0 ml tubes
6 x 5.0 ml tubes

I. Dispensing Status

Rx

J. Dosage Regimen

The recommended minimum dose is 1.1 mg/lb (2.5 mg/kg) moxidectin, once-a-month, by topical administration.

Dog Weight (lbs)	CORAXIS	Volume (mL)	Moxidectin (mg)
3 - 9	CORAXIS 9	0.4	10
9.1 - 20	CORAXIS 20	1.0	25
20.1 - 55	CORAXIS 55	2.5	62.5
55.1 - 88	CORAXIS 88	4.0	100
88.1 - 110*	CORAXIS 110	5.0	125

*Dogs over 110 lbs. should be treated with the appropriate combination of CORAXIS tubes.

K. Route of Administration

Topical

L. Species/Class

Dogs

M. Indication

CORAXIS is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis*. CORAXIS is also indicated for the treatment and control of the following intestinal parasites:

Intestinal Parasite	Intestinal Stage Adult	Intestinal Stage Immature Adult	Intestinal Stage Fourth Stage Larvae
Hookworm Species <i>Ancylostoma caninum</i>	X	X	X
Hookworm Species <i>Uncinaria stenocephala</i>	X	X	X
Roundworm Species <i>Toxocara canis</i>	X		X
Roundworm Species <i>Toxascaris leonina</i>	X		
Whipworm <i>Trichuris vulpis</i>	X		

II. EFFECTIVENESS

A. Dosage Characterization

The topically applied dose of moxidectin necessary for the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), roundworms (*Toxocara canis*, *Toxascaris leonina*), whipworms (*Trichuris vulpis*), immature adults (*A. caninum*, *U. stenocephala*), and fourth stage larvae (*A. caninum*, *U. stenocephala*, *T. canis*) has been determined to be 2.5 mg/kg, based on the studies conducted for the approval of ADVANTAGE MULTI for Dogs Topical Solution (10% imidacloprid + 2.5% moxidectin; NADA 141-251). The results of nine laboratory dosage characterization studies in dogs for ADVANTAGE MULTI for Dogs established *T. canis* as the dose limiting gastrointestinal parasite for moxidectin. Refer to the Freedom of Information (FOI) Summary for ADVANTAGE MULTI for Dogs (NADA 141-251) for this information.

B. Substantial Evidence

Because the concentration of moxidectin in this product is identical to the concentration in ADVANTAGE MULTI for Dogs (2.5% moxidectin), the substantial evidence for CORAXIS is established based on the effectiveness studies conducted for the approval of ADVANTAGE MULTI for Dogs (10% imidacloprid + 2.5% moxidectin). The results of 20 well-controlled laboratory studies in dogs provided substantial evidence of effectiveness for ADVANTAGE MULTI for Dogs for the labeled indications. Three of these studies were non-interference studies which demonstrated equivalent effectiveness of 2.5% moxidectin solution alone or in combination with imidacloprid. Neither the presence nor absence of imidacloprid interfered with the effectiveness of moxidectin against induced infections of *Dirofilaria immitis* third-stage larvae (Report #75490) and natural infections of adult *Toxocara canis* infections (Report #75312 and Report #75326). Based on the studies conducted for ADVANTAGE MULTI for Dogs, which included effectiveness of moxidectin alone against *D. immitis* and *T. canis* (the dose limiting gastrointestinal parasite), it was determined that CORAXIS is effective for the prevention of heartworm disease and for the treatment and control of roundworms, hookworms, and whipworms as described above. Refer to the Freedom of Information (FOI) Summary for ADVANTAGE MULTI for Dogs (NADA 141-251) for detailed information on these studies.

III. TARGET ANIMAL SAFETY:

Because the concentration of moxidectin in this product is identical to the concentration in ADVANTAGE MULTI for Dogs (2.5% moxidectin), the target animal safety for CORAXIS is established based on the target animal safety studies conducted for the approval of ADVANTAGE MULTI for Dogs (10% imidacloprid + 2.5% moxidectin). Refer to the Freedom of Information (FOI) Summary for ADVANTAGE MULTI for Dogs (NADA 141-251) for detailed information on these studies.

IV. HUMAN FOOD SAFETY:

This drug is intended for use in dogs. Because this new animal drug is not intended for use in food producing animals, CVM did not require data pertaining to drug residues in food (i.e., human food safety) for approval of this NADA.

V. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to CORAXIS:

“Not for human use. Keep out of reach of children.

Children should not come in contact with application sites for two (2) hours after application. Causes eye irritation. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Exposure to the product has been reported to cause headache; dizziness; and redness, burning, tingling, or numbness of the skin. Wash hands thoroughly with soap and warm water after handling.

If contact with eyes occurs, hold eyelids open and flush with copious amounts of water for 15 minutes. If eye irritation develops or persists, contact a physician. If swallowed, call poison control center or physician immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or physician. People with known hypersensitivity to benzyl alcohol or moxidectin should administer the product with caution. In case of allergic reaction, contact a physician. If contact with skin or clothing occurs, take off contaminated clothing. Wash skin immediately with plenty of soap and water. Call a poison control center or physician for treatment advice.

The Material Safety Data Sheet (MSDS) provides additional occupational safety information. For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Bayer Veterinary Services at 1-800-422-9874. For consumer questions call 1-800-255-6826.”

VI. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 514. The data demonstrate that CORAXIS when used according to the label, is safe and effective for the prevention of heartworm disease caused by *Dirofilaria immitis*, and for the treatment and control of *Ancylostoma caninum* (adults, immature adults, and fourth stage larvae), *Uncinaria stenocephala* (adults, immature adults, and fourth stage larvae), *Toxocara canis* (adults and fourth stage larvae), *Toxascaris leonina* (adults), and *Trichuris vulpis* (adults) in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 pounds.

A. Marketing Status:

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise and proper diagnosis are required to determine the existence of heartworm infections and to monitor the safe use of the product.

B. Exclusivity:

CORAXIS, as approved in our approval letter, qualifies for THREE years of marketing exclusivity beginning as of the date of our approval letter. This drug qualifies for exclusivity under section 512(c)(2)(F)(ii) of the FD&C Act because the sponsor submitted an original NADA that contains new studies that demonstrate the safety and effectiveness of CORAXIS.

C. Patent Information:

For current information on patents, see the Animal Drugs @ FDA database or the Green Book on the FDA CVM internet website.