Date of Approval: January 28, 2022

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-716

Midamox™ for Dogs

(imidacloprid + moxidectin)

Topical Solution

Dogs

Midamox™ for Dogs is indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* and the treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs. Midamox™ for Dogs kills adult fleas and is indicated for the treatment of flea infestations (*Ctenocephalides felis*). Midamox™ for Dogs is indicated for the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis.* Midamox™ for Dogs is also indicated for the treatment and control of the following intestinal parasites:

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

Sponsored by:

Norbrook Laboratories, Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-716

B. Sponsor

Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP, Northern Ireland

Drug Labeler Code: 055529

U.S. Agent Name and Address:
Melanie Archer
Norbrook Inc
9401 Indian Creek Parkway
Suite 680
Overland Park, KS 66210

C. Proprietary Name

Midamox™ for Dogs

D. Drug Product Established Name

imidacloprid + moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

100 mg/mL (10%) imidacloprid and 25 mg/mL (2.5%) moxidectin

H. How Supplied

0.4 mL, 1.0 mL, 2.5 mL, 4.0 mL, and 5.0 mL applicator tubes. Six applicator tubes/carton.

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

The recommended minimum dose is 4.5 mg/lb (10 mg/kg) imidacloprid and 1.1 mg/lb (2.5 mg/kg) moxidectin, once a month, by topical administration.

As specified in the following table, administer the entire contents of the Midamox™ for Dogs (imidacloprid + moxidectin) applicator that correctly corresponds with the body weight of the dog.

Dogs (lbs.)	**Midamox™ for Dogs**	**Volume (mL)**	**Imidacloprid (mg)**	**Moxidectin (mg)**
3-9	Midamox 9	0.4	40	10
9.1-20	Midamox 20	1.0	100	25
20.1-55	Midamox 55	2.5	250	62.5
55.1-88	Midamox 88	4.0	400	100
88.1-110*	Midamox 110	5.0	500	125

*Dogs over 110 lbs. should be treated with the appropriate combination of Midamox™ for Dogs applicators.

K. Route of Administration

Topical

L. Species/Class

Dogs

M. Indications

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Intestinal Parasite		Intestinal Stage		
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	Uncinaria stenocephala	X	X	X
Roundworm Species	*Toxocara canis*	X		X
	Toxascaris leonina	X		
Whipworm	*Trichuris vulpis*	X		

N. Reference Listed New Animal Drug (RLNAD)

Advantage Multi™ for Dogs; imidacloprid + moxidectin; NADA 141-251; Elanco US Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an

abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). The ANADA sponsor is required to show that the generic product is bioequivalent to the RLNAD, which has been shown to be safe and effective. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Norbrook Laboratories, Ltd., was granted a biowaiver for the generic product Midamox™ for Dogs (imidacloprid + moxidectin) topical solution. The generic drug product is a topical solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is Advantage Multi™ for Dogs (imidacloprid + moxidectin) topical solution, sponsored by Elanco US Inc., under NADA 141-251, and was approved for use in dogs on December 20, 2006.

III. 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 ANADA.

IV. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Midamox™ for Dogs:

Not for human use. Keep out of the 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, imidacloprid 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 Safety Data Sheet (SDS) provides additional occupational safety information. For a copy of the Safety Data Sheet (SDS), for consumer questions or to report adverse reactions call 1-866-591-5777.

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that Midamox™ for Dogs, when used according to the label, is safe and effective for the indications listed in Section I.M. above.