

Date of Approval: January 12, 2023

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-721

Midamox™ for Cats

(imidacloprid + moxidectin)

Topical Solution

Ferrets

Provides for the addition of the following indications for ferrets:
Midamox™ for Cats is indicated for the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*. Midamox™ for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. Midamox™ for Cats is also indicated for the treatment of flea infestations on ferrets.

Sponsored by:

Norbrook Laboratories Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-721

B. Sponsor

Norbrook Laboratories Ltd.
Carnbane Industrial Estate
Newry, County Down
BT35, 6QQ, United Kingdom

Drug Labeler Code: 055529

U.S. Agent Name and Address:

Melanie Archer
Norbrook, Inc.
9733 Loiret Blvd
Lenexa, KS 66219

C. Proprietary Name

Midamox™ for Cats

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 10 mg/mL (1%) moxidectin

H. How Supplied

0.4 mL applicator: 6 applicators per carton

I. Dispensing Status

Prescription (Rx)

J. Dosage Regimen

For ferrets:

The recommended minimum dose for a ferret is 9 mg/lb (20 mg/kg) imidacloprid and 0.9 mg/lb (2 mg/kg) moxidectin, once a month, by topical administration.

Ferret (lbs.)	Midamox™ for Cats	Volume (mL)	Imidacloprid (mg)	Moxidectin (mg)
2.0-4.4	Midamox™ 9	0.4	40	4

Only the 0.4 mL applicator volume (Midamox™ 9) should be used on ferrets.

K. Route of Administration

Topical

L. Species/Class

Ferrets

M. Indications

For ferrets:

Midamox™ for Cats is indicated for the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*. Midamox™ for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations. Midamox™ for Cats is also indicated for the treatment of flea infestations on ferrets.

N. Reference Listed New Animal Drug (RLNAD)

advantage multi™ for cats; imidacloprid + moxidectin; NADA 141-254; Elanco US Inc.

O. Effect of Supplement

This supplement provides for the addition of the following indications for ferrets: Midamox™ for Cats is indicated for the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*. Midamox™ for Cats kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-721, dated March 28, 2022, contains a summary of the basis for granting a biowaiver for the generic drug product Midamox™ for Cats (imidacloprid + moxidectin) topical solution.

III. HUMAN FOOD SAFETY

This drug is intended for use ferrets. 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 Cats:

HUMAN WARNINGS:

Not for human use. Keep out of the reach of children. Children should not come in contact with the application site for 30 minutes 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 safety information. For a copy of the Safety Data Sheet (SDS) or to report adverse reactions call Norbrook at 1-866-591-5777.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that Midamox™ for Cats, when used according to the label, is safe and effective for the indications listed in Section I.M. above.