

Date of Approval: August 3, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-836

MoxiShield™

(moxidectin)

Topical Solution

Beef and Dairy Cattle

For the treatment and control of internal [adult and fourth-stage larvae (L₄)] and external parasites of cattle listed in Section I.M.

Sponsored by:

Virbac AH, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-836

B. Sponsor

Virbac AH, Inc.
PO Box 162059
Fort Worth, TX 76161

Drug Labeler Code: 051311

C. Proprietary Name

MoxiShield™

D. Drug Product Established Name

moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

5 mg moxidectin/mL

H. How Supplied

33.81 fl oz/1 L bottle and 84.54 fl oz/2.5 L, 169 fl oz/5 L, and 338 fl oz/10 L containers

I. Dispensing Status

Over the Counter (OTC)

J. Dosage Regimen

MoxiShield™ (moxidectin) Pour-On is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the top of the back from the withers to the tailhead (see Figure 1). Due to the angular topline characteristic of most dairy breeds, it is recommended that all pour-on products be applied slowly to dairy cows. Apply to healthy skin avoiding any mange scabs, skin lesions, mud or manure. Treated cattle can be easily recognized by the characteristic purple color, which will remain for a short period of time after treatment. The recommended rate of administration is 1 mL for each 22 lb (10 kg) body weight which provides 0.5 mg moxidectin for each 2.2 lb (0.5 mg/kg) body weight.

K. Route of Administration

Topical

L. Species/Classes

Beef and dairy cattle

M. Indications

MoxiShield™ Pour-On when applied at the recommended dose level of 0.5 mg/2.2 lb (0.5 mg/kg) body weight is effective in the treatment and control of the following internal [adult and fourth-stage larvae (L₄)] and external parasites of cattle:

Gastrointestinal Roundworms

Ostertagia ostertagi - Adult and L₄ (including inhibited larvae)

Haemonchus placei - Adult and L₄

Trichostrongylus axei - Adult and L₄

Trichostrongylus colubriformis - Adult and L₄

Cooperia oncophora - Adult and L₄

Cooperia pectinata - Adult

Cooperia punctata - Adult and L₄

Cooperia spatulata - Adult

Cooperia surnabada - Adult and L₄

Bunostomum phlebotomum - Adult

Nematodirus helvetianus - Adult and L₄

Oesophagostomum radiatum - Adult and L₄

Lungworms

Dictyocaulus viviparus - Adult and L₄

Cattle Grubs

Hypoderma bovis

Hypoderma lineatum

Mites

Chorioptes bovis

Psoroptes ovis (*Psoroptes communis* var. *bovis*)

Lice

Linognathus vituli

Haematopinus eurytetrus

Solenopotes capillatus

Bovicola (Damalinia) bovis

Horn Flies

Haematobia irritans

Management Considerations for External Parasites: For most effective external parasite control, MoxiShield™ Pour-On should be applied to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to apply MoxiShield™ Pour-On in your location to effectively control horn flies and external parasites. MoxiShield™ Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product

should be used as part of an integrated control program utilizing other methods to provide extended control.

Persistent Activity: Moxidectin has been proven to effectively control infections and protect from reinfection with *Haemonchus placei* for 14 days after treatment, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days after treatment, and *Dictyocaulus viviparus* for 42 days after treatment. Efficacy below 90% was observed in some *Ostertagia ostertagi* persistent activity studies at 21 and 28 days posttreatment.

N. Reference Listed New Animal Drug (RLNAD)

CYDECTIN™; moxidectin; NADA 141-099; 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, Virbac AH, Inc. was granted a biowaiver for the generic product MoxiShield™ (moxidectin) pour-on. 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 CYDECTIN™ (moxidectin) pour-on, sponsored by Elanco US Inc., under NADA 141-099, and was approved for use in beef and dairy cattle on January 28, 1998.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal period, and milk discard time established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of moxidectin is 4 µg moxidectin/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 900 ppb is established for moxidectin (the marker residue) in fat (the target tissue), and 200 ppb in liver, 50 ppb in muscle, and 40 ppb in milk, under 21 CFR 556.426.

B. Withdrawal Period and Milk Discard Time

Based on a biowaiver being granted and an evaluation of the product formulation and relevant physicochemical properties with respect to residue chemistry, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of zero days and a milk discard time of zero days have been established for moxidectin in beef and dairy cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of moxidectin is on file at the Center for Veterinary Medicine, CPK1, 5001 Campus Drive, College Park, MD 20740. To obtain a copy of the analytical method, please submit a Freedom of Information request to: <https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm>.

IV. USER SAFETY

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

Warning: Not For Use In Humans. Keep this and all drugs out of the reach of children. This product can cause irritation to skin, eyes, or mucous membranes. In case of accidental skin contact and/or clothing contamination, wash skin thoroughly with soap and water and launder clothing with detergent. In case of accidental eye contact, flush eyes with copious amounts of water. When direct inhalation occurs, cleanse lungs and respiratory passages with fresh air. In case of ingestion do not induce vomiting and seek medical attention immediately. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

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 MoxiShield™, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef and dairy cattle treated with MoxiShield™ will not represent a public health concern when the product is used according to the label.