Date of Approval: January 11, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-738

DectoGard™

(doramectin topical solution)

Topical solution

Cattle

DectoGard™ pour-on solution is indicated for the treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle

Sponsored by:

Aurora Pharmaceutical, Inc.

Table of Contents

I. GENERAL INFORMATION

A. File Number

ANADA 200-738

B. Sponsor

Aurora Pharmaceutical, Inc.
1196 Highway 3 South
Northfield, MN 55057-3009

Drug Labeler Code: 051072

C. Proprietary Name

DectoGard™

D. Drug Product Established Name

doramectin topical solution

E. Pharmacological Category

Antiparasitic

F. Dosage Form

topical solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

1 L, 2.5 L, and 5 L multi-dose containers

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Administer topically at a dosage of 500 mcg doramectin per kg (227 mcg/lb) of body weight. Each mL contains 5 mg of doramectin, sufficient to treat 22 lb (10 kg) of body weight.

K. Route of Administration

Topical

L. Species/Class

Cattle

M. Indications

DectoGard™ pour-on solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle.

Gastrointestinal roundworms
Ostertagia ostertagi (adults and L_4, including inhibited larvae)
O. lyrata (adults)
Haemonchus placei (adults and L_4)
Trichostrongylus axei (adults and L_4)
T. colubriformis (adults and L_4)
Cooperia oncophora (adults[1] and L_4)
C. pectinata (adults)
C. punctata (adults and L_4)
C. surnabada (adults)
Bunostomum phlebotomum (adults)
Oesophagostomum radiatum (adults and L_4)
Trichuris spp. (adults)

[1]Efficacy below 90% was observed against adult *C. oncophora* in some clinical studies.

Lungworms (adults and fourth stage larvae)
Dictyocaulus viviparus

Eyeworms
Thelazia gulosa (adults)
T. skrjabini (adults)

Lice
Biting Lice
Bovicola (Damalinia) bovis
Sucking Lice
Haematopinus eurysternus
Linognathus vituli
Solenopotes capillatus

Grubs
Hypoderma bovis
H. lineatum

Horn Flies
Haematobia irritans

Mange Mites
Chorioptes bovis
Sarcoptes scabiei

Doramectin topical solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*,

Ostertagia ostertagi, and *Oesophagostomum radiatum* for 28 days; and *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment.

Doramectin topical solution has been proved to effectively control infestations and to protect cattle from reinfestation with *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment.

N. Reference Listed New Animal Drug (RLNAD)

DECTOMAX®; doramectin topical solution; NADA 141-095; Zoetis 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, Aurora Pharmaceutical, Inc., was granted a biowaiver for the generic product DectoGard™ (doramectin topical solution) 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 DECTOMAX® (doramectin topical solution), sponsored by Zoetis Inc., under NADA 141-095, and was approved for use in cattle on September 16, 1997.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal period 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 doramectin is 0.75 µg/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 100 ppb is established for doramectin (the marker residue) in cattle liver (the target tissue), and a tolerance of 30 ppb is established for doramectin (the marker residue) in cattle muscle, under 21 CFR 556.222.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 45 days has been

established for doramectin in cattle treated with doramectin pour-on solution at a dose of 500 µg/kg (227 µg/lb) of body weight.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of doramectin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. 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 DectoGard™:

WARNING:
Flammable! Keep away from heat, sparks, open flame, and other sources of ignition. Not for human use. Keep out of reach of children. The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain an SDS, call 1-888-215-1256.

DectoGard™ pour-on solution for cattle may be irritating to human skin and eyes, and users should be careful not to apply it to themselves or to other persons. Operators should wear protective clothing including a long-sleeved shirt, protective gloves, and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

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 DectoGard™, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

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