Date of Approval: May 25, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-750

Doraject™

(doramectin injection)

Injectable Solution

Cattle and Swine

Cattle: Doraject™ injectable solution is indicated for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. Doraject™ injectable solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.
Swine: Doraject™ injectable solution is indicated for treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

Sponsored by:

Cronus Pharma Specialities India Private Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-750

B. Sponsor

Cronus Pharma Specialities India Private Ltd.
Sy No-99/1, M/s GMR Hyderabad
Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy,
Hyderabad, Telangana, 501218, India

Drug Labeler Code: 069043

C. Proprietary Name

Doraject™

D. Drug Product Established Name

doramectin injection

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg/mL

H. How Supplied

100 mL, 250 mL and 500 mL multi-dose, rubber-stoppered glass vials

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

Cattle: 1 mL (10 mg doramectin) per 110 lb of body weight (200 mcg/kg) administered by subcutaneous (SC) or intramuscular (IM) injection in the neck region.

Swine: 1 mL (10 mg doramectin) per 75 lb of body weight (300 mcg/kg) administered by IM injection only.

K. Route of Administration

Cattle – subcutaneous or intramuscular
Swine – intramuscular

L. Species

Cattle and swine

M. Indications

Cattle: Doraject™ injectable solution is indicated for the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites.

Gastrointestinal Roundworms (adults and fourth stage larvae)
- *Ostertagia ostertagi* (including *inhibited larvae)*
- *O. lyrata*
- *Haemonchus placei*
- *Trichostrongylus axei*
- *T. colubriformis*
- *T. longispicularis*[1]
- *Cooperia oncophora*
- *C. pectinata*[1]
- *C. punctata*
- *C. surnabada* (syn. *mcmasteri*)
- *Bunostomum phlebotomum*[1]
- *Strongyloides papillosus*[1]
- *Oesophagostomum radiatum*
- *Trichuris* spp.[1]

Lungworms (adults and fourth stage larvae)
- *Dictyocaulus viviparus*

Eyeworms (adults)
- *Thelazia* spp.

Grubs (parasitic stages)
- *Hypoderma bovis*
- *H. lineatum*

Sucking lice
- *Haematopinus eurysternus*
- *Linognathus vituli*
- *Solenopotes capillatus*

Mange Mites
- *Psoroptes bovis*
- *Sarcoptes scabiei*

[1]adults

Doraject™ injectable solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Swine: Doraject™ injectable solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, kidney worms, sucking lice, and mange mites.

Gastrointestinal Roundworms (adults and fourth stage larvae)
- *Ascaris suum*
- *Oesophagostomum dentatum*
- *Oesophagostomum quadrispinulatum*[1]
- *Strongyloides ransomi*[1]
- *Hyostrongylus rubidus*[1]

Lungworms (adults)
- *Metastrongylus* spp.

Kidney worms (adults)
- *Stephanurus dentatus*

Mange Mites (adults and immature stages)
- *Sarcoptes scabiei var. suis*

Sucking Lice (adults and immature stages)

[1]adults | *Haematopinus suis*

N. Reference Listed New Animal Drug (RLNAD)

DECTOMAX®; doramectin injection; NADA 141-061; 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, Cronus Pharma Specialities India Private Ltd., was granted a biowaiver for the generic product Doraject™ (doramectin injection). The generic drug product is an injectable 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 injection), sponsored by Zoetis Inc., under NADA 141-061, and was approved for use in cattle on July 30, 1996, and in swine on September 18, 1997.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for cattle and swine:

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 (21 CFR 556.222). The tolerances established for the RLNAD apply to the generic product. A tolerance of 300 ppb is established for doramectin (marker residue) in cattle liver (target tissue), a tolerance of 30 ppb is established for doramectin in cattle muscle, and a tolerance of 160 ppb is established f or doramectin (the marker residue) in swine liver (target tissue), under 21 CFR 556.222.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 35 days has been established for doramectin in cattle treated with doramectin injection as a single subcutaneous or intramuscular injection at a dose of 200 µg/kg body weight. A withdrawal period of 24 days has been established for doramectin in swine treated with doramectin injection as a single intramuscular injection at a dose of 300 µg/kg 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 Doraject™:

WARNINGS:

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

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 Doraject™, 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 and swine treated with Doraject™ will not represent a public health concern when the product is used according to the label.