DORAJECT- doramectin injection, solution
Cronus Pharma LLC

Doraject™
(doramectin injection)

Antiparasitic
1% injectable solution for cattle and swine
10 mg/mL

PRODUCT DESCRIPTION:

Doraject™ injectable solution (doramectin injection) is a ready-to-use, colorless to pale yellow, sterile solution containing 1% w/v doramectin (10 mg/mL). In cattle, Doraject™ is formulated to deliver the recommended dosage (200 mcg/kg of body weight) when given by subcutaneous (SC) or intramuscular (IM) injection at the rate of 1 mL/110 lb of body weight. In swine, Doraject™ is formulated to deliver the recommended dosage (300 mcg/kg of body weight) when given by IM injection at the rate of 1 mL/75 lb of body weight.

PRODUCT CHARACTERISTICS:

Doraject™ injectable solution is a highly active, broad-spectrum parasiticide for parenteral administration to cattle and swine. It contains doramectin, a novel fermentation-derived macrocyclic lactone. Doramectin is isolated from fermentations of selected strains derived from the soil organism *Streptomyces avermitilis*.

A primary mode of action of macrocyclic lactones is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Macrocyclic lactones bind to receptors that increase membrane permeability to chloride ions. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods and causes paralysis and death of the parasites. In mammals, the neuronal receptors to which macrocyclic lactones bind are localized within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

One dose of Doraject™ injectable solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle and swine.

Studies have demonstrated the safety margin of doramectin injection in cattle and swine. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose, or in swine given up to 10 times the recommended dose. Studies also demonstrated safety in neonatal calves and piglets treated with up to 3 times the recommended dose. In males (bulls and boars) and females (cows and sows during folliculogenesis, implantation, organogenesis, and through gestation), a dose 3 times the recommended dose had no effect on breeding performance.

PRODUCT INDICATIONS:

Cattle: Doraject injectable solution is indicated for the treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, eyeworms, grubs (see PRECAUTIONS), sucking lice (see PRECAUTIONS), and mange mites. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal Roundworms	Lungworms (adults and fourth stage larvae)
(adults and fourth stage larvae)	*Dictyocaulus viviparus*
Ostertagia ostertagi (including inhibited larvae)	Eyeworms (adults)
O. lyrata	*Thelazia* spp
Haemonchus placei	Grubs (parasitic stages)
Trichostrongylus axei	*Hypoderma bovis*
T. colubriformis	*H. lineatum*
T. longispicularis[1]	Sucking Lice
Cooperia oncophora	*Haematopinus eurysternus*
C. pectinata[1]	*Linognathus vituli*
C. punctata	*Solenopotes capillatus*
C. surnabada (syn. mcmasteri)	Mange Mites
Bunostomum phlebotomum[1]	*Psoroptes bovis*
Strongyloides papillosus[1]	*Sarcoptes scabiei*
Oesophagostomum radiatum Trichuris spp.[1]	[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, lungworms, kidney worms, sucking lice (see PRECAUTIONS), and mange mites. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal Roundworms	Lungworms (adults)
(adults and fourth stage larvae)	*Metastrongylus* spp.
Ascaris suum	Kidney Worms (adults)
Oesophagostomum dentatum	*Stephanurus dentatus*
Oesophagostomum quadrispinulatum1	Mange Mites (adults and immature stages)
Strongyloides ransomi1	*Sarcoptes scabiei var. suis*
Hyostrongylus rubidus1	Sucking Lice (adults and immature stages)
[1]adults	*Haematopinus suis*

DOSAGE:

Cattle: Administer Doraject™ injectable solution (doramectin injection) at the

recommended dosage of 200 mcg doramectin per kg (91 mcg/lb) of body weight. Each mL of Doraject™ contains 10 mg of doramectin, 2.5 mg of phenol, and 215 mg of ethyl oleate in a sesame oil vehicle, sufficient to treat 110 lb (50 kg) of body weight.

Body Weight (lb)	Dose (mL)
110	1
220	2
330	3
440	4
550	5
660	6
770	7
880	8
990	9
1,100	10

Swine: Administer Doraject™ injectable solution at the recommended dosage of 300 mcg doramectin per kg (136 mcg/lb) of body weight. Each mL of Doraject™ contains 10 mg of doramectin, 2.5 mg of phenol, and 215 mg of ethyl oleate in a sesame oil vehicle, sufficient to treat 75 lb (34 kg) of body weight.

Body Weight (lb)	Dose (mL)
15	0.2
30	0.4
45	0.6
60	0.8
75	1.0
150	2.0
225	3.0
300	4.0
375	5.0
450	6.0

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

RECOMMENDED TREATMENT PROGRAM FOR SWINE:

To effectively initiate control of mange and sucking lice in swine, it is important to treat all animals in the herd. After initial treatment, use Doraject™ regularly as follows:

Breeding Animals:

Sows: Treat 7–14 days prior to farrowing to minimize exposure of piglets to mites and sucking lice.

Gilts: Treat 7–14 days prior to breeding. Treat 7–14 days prior to farrowing.

Boars: Treat a minimum of 2 times per year.

Feeder Pigs: Treat any new feeder pigs upon arrival at farm or before placement in clean quarters.

Weaners, Growers, Finishers: Weaners and grow-out/finisher pigs should be treated before placement in clean quarters.

For effective mange elimination, care must be taken to prevent reinfestation from exposure to untreated animals or contaminated facilities.

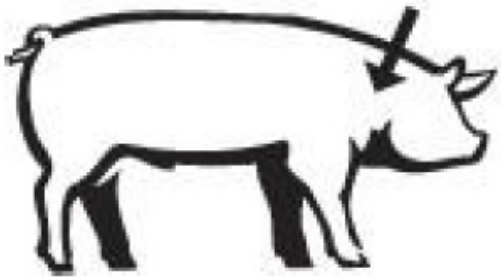
ADMINISTRATION:

Dry, sterile equipment and aseptic procedures should be used when withdrawing and administering Doraject™ (doramectin injection). For multiple treatments either automatic injection equipment or an aspirating needle should be used.

Cattle:

Administer Doraject™ injectable solution by SC or IM route. Injections should be made using a 16 gauge needle for adult cattle or an 18 gauge needle for young animals. Needles 1/2– 3/4" in length are suggested for SC administration. A 1-1/2" needle is suggested for IM administration. SC injections should be administered under the loose skin in front of or behind the shoulder. IM injections should be administered into the muscular region of the neck. Beef Quality Assurance guidelines recommend SC administration as the preferred route.

Swine:



Administer Doraject™ injectable solution by the IM route. Inject in the neck region using an 18 gauge × 1" needle for young animals; a 16 gauge × 1-1/2" needle for sows and boars. To accurately meter doses administered to piglets, use of a tuberculin syringe and 20 gauge × 1" needle is recommended.

WARNINGS:

Not for human use. Keep out of reach of children. To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Cronus Pharma LLC at 1-844-227-6687 (1-844-2-CRONUS).

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

OTHER WARNINGS:

Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers. Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance. Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method). A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

RESIDUE WARNINGS:

Cattle: Do not slaughter for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Swine: Do not slaughter for human consumption within 24 days of treatment.

PRECAUTIONS:

Doraject™ has been developed specifically for use in cattle and swine only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

For SC injection in cattle only. For IM injection in swine and cattle. This product is approved for the treatment and control of sucking lice. For treatment of biting lice in cattle, use of doramectin topical solution is recommended.

Doraject™ is highly effective against all stages of cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble) season.

Destruction of *Hypoderma larvae* (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *H. lineatum* when it is in the tissue surrounding the gullet may cause bloat; Killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis.

These reactions are not specific to treatment with Doraject™, but can occur with any successful treatment of grubs. Cattle should be treated either before or after these stages of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Doraject™ after the end of the heel fly season may be re-treated with Doraject™ during the winter for internal parasites, mange mites, or sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

ENVIRONMENTAL SAFETY:

Studies indicate that when doramectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free doramectin may adversely affect fish and certain aquatic organisms. Do not permit water runoff from feedlots to enter streams or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

As with other avermectins, doramectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

STORAGE CONDITIONS

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Use this product within 90 days of the first puncture and maximum allowable punctures are given in the below table.

If more than the maximum number of punctures is anticipated, the use of multi-dosing equipment is recommended. When using a draw-off spike or needle with bore diameter larger than 16-guage, discard any product remaining in the vial immediately after use.

Fill Volume	Allowable Punctures
100mL	28
250mL	70
500mL	141

HOW SUPPLIED:

Doraject™ (doramectin injection) is available in 100-mL, 250-mL, and 500-mL multi-dose, rubber-stoppered glass vials.

Approved by FDA under ANADA # 200-750

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Not for human use.

Restricted Drug (CA) Use only as directed.

Manufactured for:
Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)
Made in India.
November 2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-037-01

Doraject™

(doramectin injection)

Antiparasitic

1% injectable solution for cattle and swine

10 mg/mL

Approved by FDA under ANADA # 200-750

Net Contents: 100 mL

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-037-25

Doraject™

(doramectin injection)

Antiparasitic

1% injectable solution for cattle and swine

10 mg/mL

Approved by FDA under ANADA # 200-750

Net Contents: 250 mL

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-037-05

Doraject™

(doramectin injection)

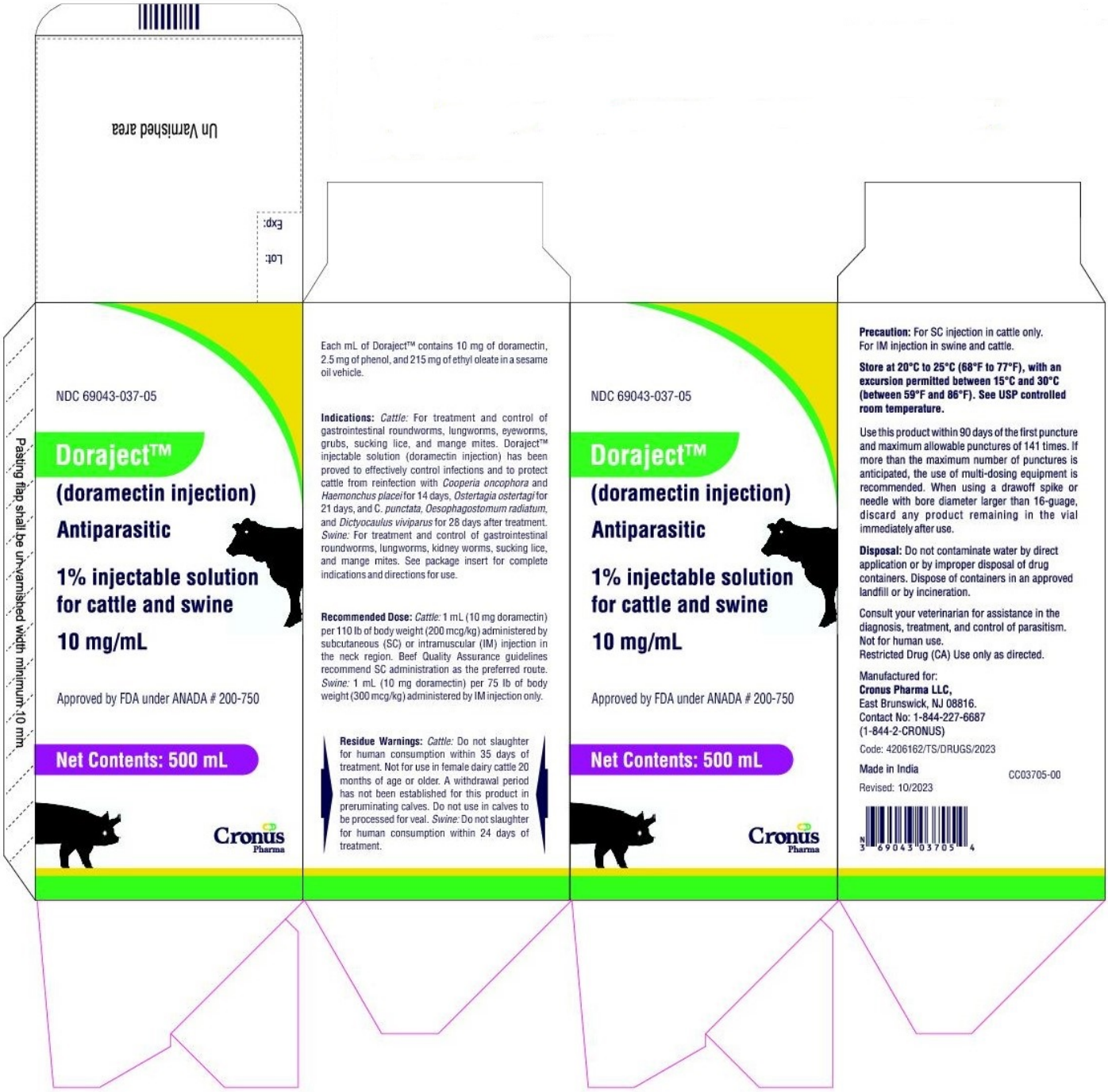
Antiparasitic

1% injectable solution for cattle and swine

10 mg/mL

Approved by FDA under ANADA # 200-750

Net Contents: 500 mL



DORAJECT

doramectin injection, solution

Product Information			
Product Type	OTC ANIMAL DRUG	**Item Code (Source)**	NDC:69043-037
Route of Administration	INTRAMUSCULAR, SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

DORAMECTIN (UNII: KGD7A54H5P) (DORAMECTIN - UNII:KGD7A54H5P)	DORAMECTIN	10 mg in 1 mL

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-037-01	100 mL in 1 VIAL, MULTI-DOSE		
2	NDC:69043-037-25	250 mL in 1 VIAL, MULTI-DOSE		
3	NDC:69043-037-05	500 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200750	08/17/2023	

Labeler - Cronus Pharma LLC (079421067)

Registrant - Cronus Pharma Specialities India Private Limited (876818318)

Establishment

Name	Address	ID/FEI	Business Operations
Cronus Pharma Specialities India Private Limited		876818318	analysis, manufacture, label, pack

Revised: 12/2023 Cronus Pharma LLC