

Date of Approval: JUN 30

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-095

DECTOMAX (doramectin) Pour-On

To extend the period of persistent effect for *Cooperia oncophora* and *Dictyocaulus viviparus* from 21 to 28 days and for *Cooperia punctata* from 28 to 35 days.

Sponsored by:
Pfizer Inc

1. GENERAL INFORMATION

- a. File Number: NADA 141-095
- b. Sponsor: Pfizer, Inc.
235 East 42nd St.
New York, NY 10017
- Drug Labeler Code: 000069
- c. Established Name: Doramectin
- d. Proprietary Name: DECTOMAX (doramectin) Pour-On
- e. Dosage Form: Solution
- f. How Supplied: 250 mL, 1 liter, 2.5 liter, and 5 liter containers
- g. How Dispensed: Over-the-Counter (OTC)
- h. Amount of Active Ingredients: 5 mg doramectin/mL
- i. Route of Administration: Topical
- j. Species/Class: Cattle
- k. Recommended Dosage: 500 mcg/kg (5 mL/110 lb body weight)
- l. Pharmacological Category: Antiparasitic
- m. Indications: For the treatment and control of the following in cattle.

Gastrointestinal Roundworms

<i>Ostertagia ostertagi</i>	Adults and fourth-stage larvae
<i>Ostertagia ostertagi</i>	Inhibited fourth-stage larvae
<i>Ostertagia lyrata</i>	Adults
<i>Haemonchus placei</i>	Adults and fourth-stage larvae
<i>Trichostrongylus axei</i>	Adults and fourth-stage larvae
<i>Trichostrongylus colubriformis</i>	Adults and fourth-stage larvae
<i>Cooperia oncophora</i> ¹	Adults and fourth-stage larvae
<i>Cooperia punctata</i>	Adults and fourth-stage larvae
<i>Cooperia pectinata</i>	Adults
<i>Cooperia surnabada</i>	Adults
<i>Bunostomum phlebotomum</i>	Adults
<i>Oesophagostomum radiatum</i>	Adults and fourth-stage larvae
<i>Trichuris</i> spp.	Adults

¹Efficacy below 90% was observed against adult *Cooperia oncophora* in some clinical studies

Lungworms

Dictyocaulus viviparus

Adults and fourth-stage larvae

Eyeworms

Thelazia gulosa

Adults

Thelazia skrjabini

Adults

Grubs

Hypoderma bovis

Hypoderma lineatum

Sucking Lice

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Biting Lice

Damalinia bovis

Mange Mites

Chorioptes bovis

Sarcoptes scabiei

Horn Flies

Haematobia irritans

DECTOMAX Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with: *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days after treatment, *Ostertagia ostertagi*, *Cooperia punctata*, and *Oesophagostomum radiatum* for 28 days after treatment and *Haemonchus placei* for 35 days after treatment.

- n. Effect of Supplement: To extend the persistent effect periods for *Cooperia punctata* from 28 to 35 days after treatment and *Dictyocaulus viviparus* and *Cooperia oncophora* from 21 to 28 days after treatment. At this time, the labeling is being revised to reflect updated environmental information.

2. EFFECTIVENESS

a. Dose Characterization

Effectiveness studies were presented in the original NADA 141-095 FOI Summary approval dated September 16, 1997, establishing the recommended effective dose of DECTOMAX Pour-On for the treatment and control of internal and external parasites.

b. Substantial Evidence for Persistent Effectiveness against Endoparasites

The original approval for the persistent effect of DECTOMAX Pour-On was demonstrated by two studies (1231C-60-95-199 and 1231C-60-95-204) that appear in the original FOI Summary dated September 16, 1997. Additionally, there were four studies (5231E-03-92-070, 5232C-03-94-090, 5232C-03-94-092, and 5232C-03-94-097) conducted in the European Union (EU) that were submitted with the original approval that were considered supportive, but not reported in the FOI. An additional indication for the persistent effect against *Haemonchus placei* for up to 35 days after treatment is discussed in a supplemental FOI Summary dated August 10, 1999. These studies were evaluated using arithmetic means. Subsequent to the original review, the VICH guidance #90 "Effectiveness of Anthelmintics: General Recommendations VICH GL7" was finalized March 26, 2001. It allowed for the evaluation of parasite effectiveness studies using geometric means and the consideration of studies conducted in the member countries. This supplemental application allows for these six studies to be reevaluated using geometric means and the persistent effect period adjusted accordingly. All six of these studies were reevaluated using geometric means. Two additional studies (2239B-60-97-065 and 2239B-60-97-094) conducted subsequent to the original approval were submitted with this supplement and evaluated using geometric means.

For each study, percent efficacy was determined by comparing the geometric mean worm counts of the treated groups with those of an untreated control group for each parasite species present in at least six adequately infected control animals. The differences in geometric mean numbers of parasite counts between the treated groups and the controls were tested using a one-way analysis of variance. The period of persistent activity was defined as the time during which the effectiveness against a genus species was $\geq 90\%$.

For an indication to be granted, a minimum of two studies is required that have the following: an adequate level of infection in 6 control animals, a statistically significant difference between treated and control animals at $P < 0.05$, and 90% efficacy using geometric means for each genus species of parasite and at each persistent effect period. If there are more than 2 studies, then the geometric means of the percent efficacy against a genus species of parasite from each study is added together and divided by the number of studies with that genus species of parasite. If this average is greater than or equal to 90% then the claim may be granted. These eight studies were evaluated using geometric means as described above. The overall percent efficacy from these studies for *Cooperia oncophora* at 28 days is 92.1% (six studies) and *Dictyocaulus viviparus* at 28 days is 95.6% (six studies). There were only two studies for *Cooperia punctata* and both demonstrated percent efficacy $\geq 90\%$ for 35 days after treatment. The extension of the persistent effect periods for *Cooperia oncophora* is from 21 to 28 days after treatment, *Dictyocaulus viviparus* from 21

to 28 days after treatment and *Cooperia punctata* from 28 to 35 days after treatment. The eight trials are individually summarized below.

B.1 Dose Confirmation Study 1231C-60-95-199

- 1) Investigator: Edward G. Johnson
24007 Highway 20/26
Parma, Idaho
- 2) General Design:
 - a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Ten (10) per group. Cattle were 4 to 6 months old and weighed 127 to 251 kg at the start of the study.
 - c. Nematode isolate: *Dictyocaulus viviparus* 1994 field isolate from Wisconsin, *Ostertagia ostertagi*, *Cooperia punctata*, and *C. oncophora* 1995 field isolates from Louisiana and Idaho
 - d. Controls: Animals in the negative control group (T1) received saline.
 - e. Procedure: Forty-two (42) animals were weighed and randomly allocated to a saline-treated group (T1, 10 animals) or to one of three doramectin-treated groups (T2 to T4, 10 animals each) on Day 0 or to serve as one of the two larvae viability monitor animals. On Day 0, animals in Groups T1 and T2 were treated topically with saline (1 mL/10 kg BW) or doramectin pour-on (500 µg/kg BW), respectively. Groups T3 and T4 were treated with doramectin pour-on in an identical manner on Days 7 and 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 14 to 35 with infective nematode larvae (approximately 50, 1,000, and 1,000 of *D. viviparus*, *O. ostertagi*, and *C. punctata*). Other nematode species were present as contaminants of the inocula. Animals from Groups T1 to T4 were euthanized and necropsied on Days 49 and 50 for determination of worm counts.
- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.1.

Table 2.1 1231C-60-95-199 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	224 (100-380)	28 days	99.7
<i>Dictyocaulus viviparus</i>	23 (0-75)	28 days	100.0
<i>Cooperia punctata</i>	243 (120-504)	35 days	94.0

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.2 Dose Confirmation Study 1231C-02-95-204

- 1) Investigator: R. K. Pritchard, Ph.D.
Institute of Parasitology
McGill University
Ste-Anne de Bellvue
Quebec, Canada
- 2) General Design:
- a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Ten (10) per group. Cattle were 4 to 6 months old and weighed 90 to 216 kg at the start of the study.
 - c. Nematode isolate: *Dictyocaulus viviparus* 1995 field isolate from Wisconsin; *Ostertagia ostertagi* and *Cooperia punctata* 1995 field isolates from Louisiana; *C. oncophora* 1995 field isolate from Maryland and Louisiana
 - d. Controls: Animals in the negative control group (T1) received saline.
 - e. Procedure: Forty-two (42) animals were weighed and randomly allocated to a saline-treated group (T1, 10 animals) or to one of three doramectin-treated groups (T2 to T4, 10 animals each) on Day 0 or to serve as one of the two larvae viability monitor animals. On Day 0, animals in Groups T1 and T2 were treated topically with saline (1 mL/10 kg BW) or doramectin pour-on (500 µg/kg BW), respectively. Groups T3 and T4 were treated with doramectin pour-on in an identical manner on Days 7 and 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 14 to 35 with infective nematode larvae (approximately 50, 1,000, and 1,000 of *D. viviparus*, *O. ostertagi*, and *C. punctata*). Other nematode species were present as contaminants of the inocula. Animals from Groups T1 to T4 were euthanized and necropsied on Days 49 and 51 for worm counts.
- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.2.

Table 2.2 1231C-02-95-204 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	1060 (0-5200)	28 days	91.8
<i>Dictyocaulus viviparus</i>	4 (0-30)	28 days	86.0
<i>Cooperia punctata</i>	512 (50-1900)	35 days	98.4

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.3 Dose Confirmation Study 2239B-60-97-065

- 1) Investigator: Larry Smith, D.V.M.
Research and Development Inc.
108 Davis Street
Lodi, WI
- 2) General Design:
- a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Ten (10) per group. Cattle were 2 to 6 months old and weighed 74 to 171 kg at the start of the study.
 - c. Nematode isolate: *Dictyocaulus viviparus* 1997 field isolate from Mississippi
 - d. Controls: Animals in the negative control group (T1) received saline.
 - e. Procedure: Forty-two (42) animals were weighed and randomly allocated to a saline-treated group (T1, 10 animals), the doramectin-treated groups (T2, T3, T4, 10 animals each) on Day 0 or to serve as one of the two larvae viability monitor animals. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Groups T2, T3, and T4 were treated with doramectin pour-on (500 mcg/kg) on Day 0, 7, or 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 28 to 42 with infective nematode larvae (approximately 50 of *D. viviparus*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 56 and 57 for determination of worm counts.
3. Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.3.

Table 2.3 2239B-60-97-065 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Dictyocaulus viviparus</i>	39 (3-118)	28 days	87.4

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.4 Dose Confirmation Study 2239B-60-97-094

- 1) Investigator: Bert E. Stromberg, Ph.D.
205 Veterinary Science
1971 Commonwealth Avenue
University of Minnesota
St. Paul, MN

- 2) General Design:
 - a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Ten (10) per group. Cattle were 2 to 6 months old and weighed 131 to 214 kg at the start of the study.
 - c. Nematode isolate: *Dictyocaulus viviparus* 1996 field isolate from Wisconsin
 - d. Controls: Animals in the negative control group (T1) received saline.
 - e. Procedure: Forty-two (42) animals were weighed and randomly allocated to a saline-treated group (T1), the doramectin-treated groups (T2, T3, T4) on Day 0 or to serve as one of the two larva viability monitor animals. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Groups T2, T3, and T4 were treated with doramectin pour-on (500 mcg/kg) on Day 0, 7, or 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 28 to 42 with infective nematode larvae (approximately 50 of *D. viviparus*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 56 and 57 for determination of worm counts.

- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.4.

Table 2.4 2239B-60-97-094 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Dictyocaulus viviparus</i>	10 (3-22)	28 days	100.0

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.5 Dose Confirmation Study 5232E-03-92-070

- 1) Investigator: C. Hong, Ph.D.
M.A.F.F. Central Veterinary Laboratory
Halls Farm, New Haw
Weybridge
Surry, England
- 2) General Design:
- a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Ten (10) or seven (7) per group. Cattle were 3 to 6 months old and weighed 94 to 134 kg at the start of the study.
 - c. Nematode isolate: *Cooperia oncophora* Pfizer in-house culture
 - d. Controls: Animals in the negative control group (T1) received no treatment.
 - e. Procedure: Thirty one (31) animals were weighed and randomly allocated to a saline-treated group (T1, 10 animals), the doramectin-treated groups (T2, T3, T4, 7 animals each). No physical contact was permitted between groups. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Groups T2, T3, and T4 were treated with doramectin pour-on (500 µg/kg) on Day 0, 7, or 14, respectively.
- Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 14 to 28 with infective nematode larvae (approximately 1,000 of *C. oncophora*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 42 and 43 for determination of worm counts.
- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.5.

Table 2.5 5232E-03-92-70 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	9200 (2950-13250)	28 days	90.2

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.6 Dose Confirmation Study 5232C-03-94-090

1) Investigator: J. Brebner, Ph.D.
Moredun Animal Health Ltd.
408, Gilmerton Road
Edinburgh
Scotland

2) General Design:

- a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
- b. Animals: Twelve (12) per group. Cattle weighed 77 to 132 kg at the start of the study.
- c. Nematode isolates: *Ostertagia ostertagi*, Ridgeway Science Ltd Culture; *Cooperia oncophora*, Pfizer in-house culture
- d. Controls: Animals in the negative control group (T1) received no treatment.
- e. Procedure: Forty-eight (48) animals were weighed and randomly allocated to a saline-treated group (T1, 12 animals), or one of the doramectin-treated groups (T2, T3, T4, 12 animals each) on Day 0. No physical contact was permitted between groups. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Animals in Groups T2, T3, and T4 were treated with doramectin pour-on (500 mcg/kg) on Day 0, 7, or 14, respectively.

Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 14 to 35 with infective nematode larvae (approximately 1,000 of *O. ostertagi* and 1,000 *C. oncophora*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 49 and 50 for determination of worm counts.

3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.6.

Table 2.6 5232C-03-94-90 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	12686 (7450-17350)	28 days	99.8

4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.7 Dose Confirmation Study 5232C-03-94-092

- 1) Investigator: D. J. Burden, Ph.D.
Park Farm
St. Braivels
Coleford
Gloucestershire, England

- 2) General Design:
 - a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Fourteen (14) or twelve (12) per group. Cattle were 3 to 6 months old and weighed 85 to 115 kg at the start of the study.
 - c. Nematode isolates: *Dictyocaulus viviparus*, *Ostertagia ostertagi*, and *Cooperia oncophora* Pfizer in-house cultures
 - d. Controls: Animals in the negative control group (T1) received no treatment.
 - e. Procedure: Fifty (50) animals were weighed and randomly allocated to a saline-treated group (T1, 14 animals), or one of the doramectin-treated groups (T2, T3, T4, 12 animals each) on Day 0. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Groups T2, T3, and T4 were treated with doramectin pour-on (500 mcg/kg) on Day 0, 7, or 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 21 to 48 with infective nematode larvae (approximately 50 of *D. viviparus*, 1,000 *O. ostertagi*, and 1,000 *C. oncophora*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 56 and 57 for determination of worm counts.

- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.7.

Table 2.7 5232C-03-94-092 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	9194 (4200-16450)	27 days	96.4
<i>Dictyocaulus viviparus</i>	176 (27-396)	27 days	100.0

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

B.8 Dose Confirmation Study 5232C-03-94-097

- 1) Investigator: D. J. Burden, Ph.D.
Park Farm
St. Braivels
Coleford
Gloucestershire, England

- 2) General Design:
 - a. Purpose: To evaluate the persistent efficacy of doramectin pour-on, administered topically at a dosage of 500 mcg/kg body weight against artificially induced nematode infections.
 - b. Animals: Fourteen (14) or twelve (12) per group. Cattle were 3 to 6 months old and weighed 85 to 115 kg at the start of the study.
 - c. Nematode isolates: *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Cooperia oncophora* Pfizer in-house cultures
 - d. Controls: Animals in the negative control group (T1) received no treatment.
 - e. Procedure: Fifty (50) animals were weighed and randomly allocated to a saline-treated group (T1, 14 animals), or one of the doramectin-treated groups (T2, T3, T4, 12 animals each) on Day 0. No physical contact was permitted between groups. On Day 0, animals in Group T1 were treated topically with saline (1 mL/10 kg BW). Groups T2, T3, and T4 were treated with doramectin pour-on (500 mcg/kg) on Day 0, 7, or 14, respectively. Each of the animals in Groups T1 to T4 was artificially challenged daily on Days 21 to 48 with infective nematode larvae (approximately 50 of *D. viviparus*, 1,000 *O. ostertagi*, and 1,000 *C. oncophora*). Animals from Groups T1 to T4 were euthanized and necropsied on Days 56 and 57 for determination of worm counts.

- 3) Results: The percent efficacy based on geometric mean in the doramectin-treated group compared to the non-medicated group is summarized in Table 2.8.

Table 2.8 5232C-03-94-097 – Persistent Effect Periods and Percent Efficacy

Nematode Species	Geometric Mean and range in Controls	Persistent Effect Period	% Efficacy of DECTOMAX Pour-On
<i>Cooperia oncophora</i>	8555 (1500-16800)	27 days	74.8
<i>Dictyocaulus viviparus</i>	133 (41-403)	27 days	99.9

- 4) Adverse Events: There were no adverse events observed at any time during the study for any of the doramectin-treated cattle.

3. TARGET ANIMAL SAFETY

No further target animal safety data were required from the original approval as discussed in the parent NADA 141-095 FOI Summary approval dated September 16, 1997.

4. HUMAN SAFETY

No further human food safety data were required from the original approval as discussed in the parent NADA 141-095 FOI Summary approval dated September 16, 1997. There is a 45-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and a withdrawal period has not been established for pre-ruminating calves.

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that DECTOMAX Pour-On for Cattle when administered once at 500 mcg doramectin/kg body weight is safe and effective for the extension of the following persistent effect periods: *Cooperia oncophora* from 21 to 28 days, *Dictyocaulus viviparus* from 21 to 28 days and for *Cooperia punctata* from 28 to 35 days.

The Agency has concluded that this product may retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did require a reevaluation of safety or effectiveness data in the parent application. Previously submitted studies were reevaluated using geometric means allowing the persistent effect period for three nematode species to be extended.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the extension of three already approved persistent effect indications listed above.

No patent information was submitted with this application.

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

- A. 250 mL, 1 liter, 2.5 liter, and 5 liter – bottle label and box carton
- B. Package insert for all container sizes

FPD Code [28
05570500]



7892000

DECTOMAX
(doramectin)

■■■ **Pour-On**

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 250 mL

NADA #141-095, Approved by FDA

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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 preweaning calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only
Store Below 30°C (86°F)

Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.

Distributed by:
Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

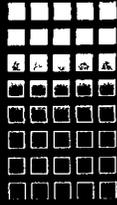
Warning: Flammable! Keep away from heat, sparks, open flames, and other sources of ignition.



05-5269-00-X10
Made in USA

111

IDECTOMAX®
Pour-On



7892000



IDECTOMAX®
(doramectin)
Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Treats 10 550-lb cattle

Net Contents: 250 mL

NADA #161-025, Approved by FDA



Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guides are provided in the following table.

Body Weight (lb) Dose (mL)

Up to 110	5 mL*
111-220	10 mL
221-330	15 mL
331-440	20 mL
441-550	25 mL
551-660	30 mL
661-770	35 mL
771-880	40 mL
881-990	45 mL
991-1100	50 mL

* Administer using an appropriate dosing gun.
For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1-110 lb of body weight.

REG-UPC



0 87219 02712 7

Indications: For treatment and control of gastrointestinal roundworms, lungworms, cyamids, grubs, biting and sucking lice, horn flies, and mango flies in cattle.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitosis. See package insert for complete instructions and directions for use.

Dectomax Pour-On has been proved to effectively control infections and to protect cattle from reinfection with Cooperia oncophora, Dicrocoelium viverrinum, and Haemonchus placei for 28 days after treatment.

Dectomax Pour-On solution provides 7 days of persistent activity against horn fly larvae. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Warnings: Prohibited: Keep away from food, feed, water, open flames, and other sources of ignition.

Dectomax Pour-On solution for cattle may be irritating to human skin and eyes. Avoid contact with mucous membranes. Do not apply to areas of skin which are irritated or broken.

Handling Warnings: Cattle must not be slaughtered for human consumption within 45 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 pharmaceutical cattle. Do not use in calves to be processed for veal.

Precautions: This product is to be applied to skin surface only. Do not administer orally or parenterally. Do not apply to areas of skin which are irritated with mud or manure.

Use Caution: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

State Safety Data Sheet (SDS): Please Refer to SDS.

Important: Do not contaminate water by direct application or improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

Not for human use.

Approved Drug (AD) Use only as directed.

Advanis Health
 Kansas, PA 19041, USA
 Div. of Pfizer Inc.
 15-2599-00-110
 Made in USA

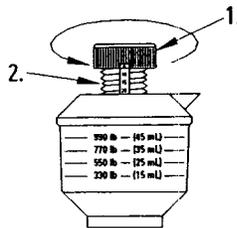
DECTOMAX®
 Pour-On

DECTOMAX®
 Pour-On

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DECTOMAX®
 Pour-On



DOSING CUP

A. Rotate the cup on the bottle neck until tight (so the spout is aligned at the mid-point on the wide side of the bottle)

B. Select the dose:

→ Twist the dosing screw ① to the desired position, so that the correct number of mL is shown at the set dose mark (② DOSAGE (mL) †).

→ The first complete turn of the dosing screw will set the dose at 10 mL (i.e. 220 lb or 100 kg of body weight): "10" shows on the screw at set dose mark ②. Each additional turn increases the dose in 5 mL increments (i.e. 110 lb or 50 kg of body weight) up to 50 mL.

C. Overfill the dosing cup by squeezing the bottle, until the level of liquid goes over the selected dose, then release the pressure. The liquid will automatically come down to the selected dose.

D. Pour the product along the back of the animal.

GODET APPLICATEUR

A. Serrer le godet en pivotant sur le col de la bouteille (pour que le godet soit correctement installé lorsque le bec est aligné avec la partie large de la bouteille).

B. Choisir une dose:

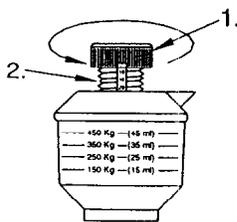
→ Tourner la vis de réglage ① jusqu'à la position désirée, pour que le nombre correct de mL soit visible à la marque de réglage de la dose (② POSOLOGIE (mL) †).

→ Le premier tour complet de la vis règle la dose à 10 mL (i.e. 100 kg ou 220 lb de poids corporel): "10" à la marque de réglage de la dose sur la vis ②. Chaque tour additionnel augmente la dose de 5 mL (50 kg ou 110 lb de poids corporel) jusqu'à 50 mL.

C. Remplir le godet applicateur, à excès, en pressant sur la bouteille jusqu'à ce que le niveau du liquide dépasse la dose choisie, et puis relâcher la pression. Le liquide retournera automatiquement à la dose choisie.

D. Verser le produit le long du dos de l'animal.

993 10-5269-00-3



7893000

DECTOMAX[®]
(doramectin)



Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 1 liter

NADA #141-095, Approved by FDA



Distributed by
Animal Health

Kenilworth, PA 19041, USA
Div. of Pfizer Inc.
NY, NY 10017

05-5271-00-X10
Made in USA



Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

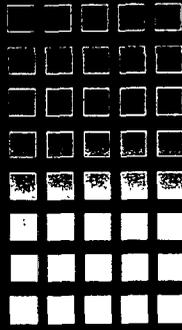
Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.



7893000

DECTOMAX[®]

(doramectin)



Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Treats 40 550-lb cattle

Net Contents: 1 liter

NADA #141-095, Approved by FDA

Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:

Body Weight (lb)	Dose (mL)
Up to 110	5 mL*
111-220	10 mL
221-330	15 mL
331-440	20 mL
441-550	25 mL
551-660	30 mL
661-770	35 mL
771-880	40 mL
881-990	45 mL
991-1100	50 mL

* Administer using an appropriate dosing gun.

For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1-110 lb of body weight.





Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Dectomax 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, rubber 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. Wash hands after use. Do not smoke or eat while handling the product.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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 pre-ruminating calves. Do not use in calves to be processed for veal.

Precautions: This product is to be applied to skin surface only. Do not administer orally or parenterally. Do not apply to areas of skin which are caked with mud or manure.

Use Conditions: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

Store Below 30°C (86°F)

Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.



Distributed by:

Animal Health

Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

TAKE TIME

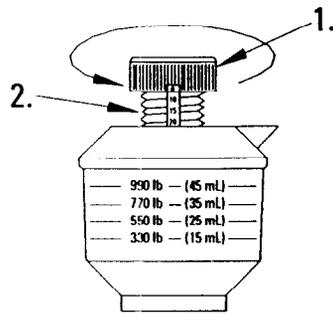


OBSERVE LABEL
DIRECTIONS

15-5271-00-X10
Made in USA

DECTOMAX[®] Pour-On

DECTOMAX[®]
Pour-On



DOSING CUP

A Rotate the cup on the bottle neck until tight (so the spout is aligned at the mid-point on the wide side of the bottle).

B Select the dose:

→ Twist the dosing screw ① to the desired position, so that the correct number of mL is shown at the set dose mark (② DOSAGE (mL) ↑)

→ The first complete turn of the dosing screw will set the dose at 10 mL (i.e. 220 lb or 100 kg of body weight): "10" shows on the screw at set dose mark ②. Each additional turn increases the dose in 5 mL increments (i.e. 110 lb or 50 kg of body weight) up to 50 mL.

C Overfill the dosing cup by squeezing the bottle, until the level of liquid goes over the selected dose, then release the pressure. The liquid will automatically come down to the selected dose.

D Pour the product along the back of the animal.

GODET APPLICATEUR

A Serrer le godet en pivotant sur le col de la bouteille (pour que le godet soit correctement installé lorsque le bec est aligné avec la partie large de la bouteille).

B Choisir une dose:

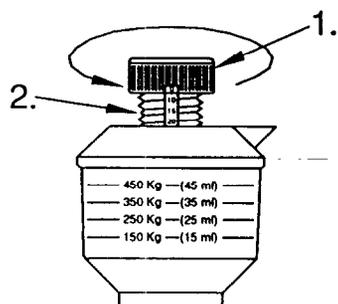
→ Tourner la vis de réglage ① jusqu'à la position désirée, pour que le nombre correct de mL soit visible à la marque de réglage de la dose (② POSOLOGIE (mL) ↑).

→ Le premier tour complet de la vis règle la dose à 10 mL (i.e. 100 kg ou 220 lb de poids corporel): "10" à la marque de réglage de la dose sur la vis ②. Chaque tour additionnel augmente la dose de 5 mL (50 kg ou 110 lb de poids corporel) jusqu'à 50 mL.

C Remplir le godet applicateur, à excès, en pressant sur la bouteille jusqu'à ce que le niveau du liquide dépasse la dose choisie, et puis relâcher la pression. Le liquide retournera automatiquement à la dose choisie.

D Verser le produit le long du dos de l'animal.

993 10-5271-00-3





Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb 10 kg of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flames, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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 premarketing calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

Protect From Light

Dispense: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.



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NY, NY 10017

05-5273-00-X10
Made in USA

7894000

DECTOMAX
(doramectin)



Pour-On

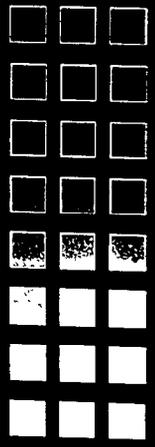
Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 2.5 liters

NADA #141-095, Approved by FDA





Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Dectomax 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, rubber 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. Wash hands after use. Do not smoke or eat while handling the product.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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.

Precautions: This product is to be applied to skin surface only. Do not administer orally or parenterally. Do not apply to areas of skin which are caked with mud or manure.

Use Conditions: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

Store Below 30°C (86°F)

Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.

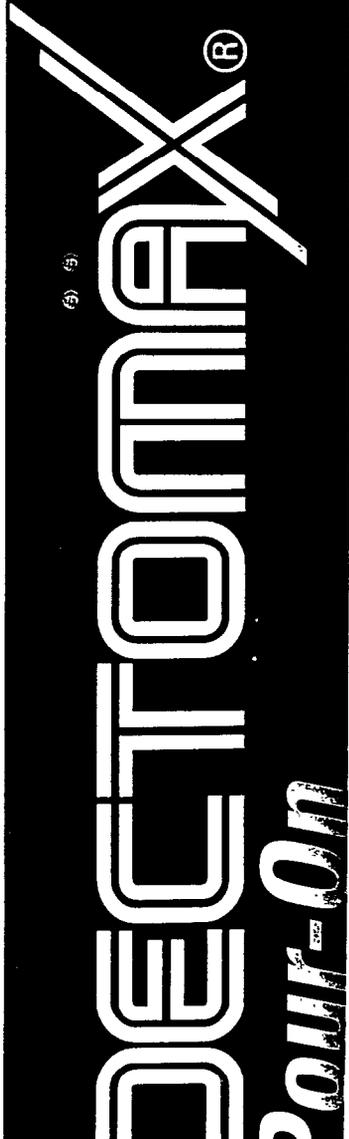


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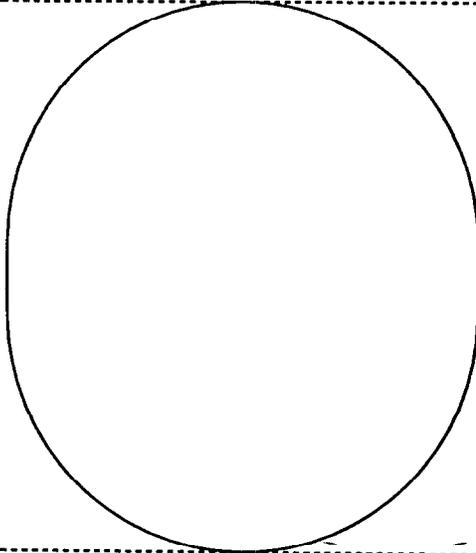
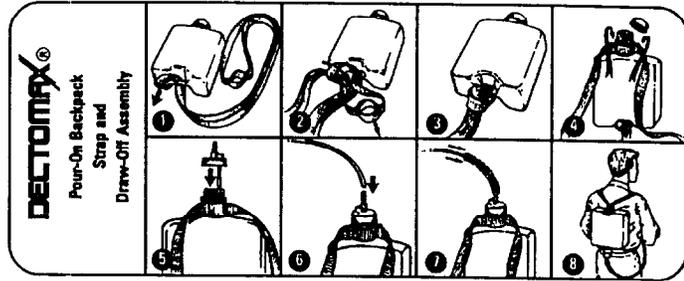
Animal Health

Exton, PA 19341, USA
Div of Pfizer Inc
NY, NY 10017

15-5273-00-X10
Made in USA

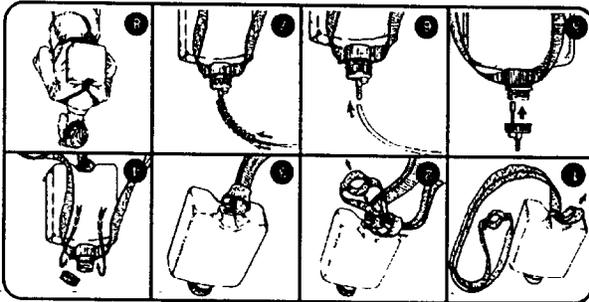


Connect the pour-on applicator to the backpack as follows.
 Attach the open end of the draw-off tubing to the pour-on applicator.
 Attach draw-off tubing to the cap with the stem. Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.
 Gently prime the pour-on applicator, checking for leaks (see insert).
 Follow manufacturer's directions for correct use and care of the equipment.
 Applicators compatible with this formulation are available for use with Dectomax Pour-On for cattle.
 Some applicators may be incompatible with this formulation.



997 10-5273-00-4

Demander l'applicateur pour la solution à verser à l'applicateur à dos comme suit:
 Fixer l'extrémité ouverte du tuyau de vidange à l'applicateur pour la solution à verser.
 Fixer le tuyau de vidange au capuchon avec la tige. Remplacer le capuchon d'expédition avec le capuchon lié au tuyau de vidange. Serrer le capuchon de vidange.
 Amorcer délicatement l'applicateur, et s'assurer qu'il n'y a aucune fuite (voir le dépliant) l'équipement.
 Suivre les indications du fabricant concernant le mode d'emploi et l'entretien de l'équipement.
 Des applicateurs compatibles avec cette préparation sont disponibles pour utilisation avec la solution à verser Dectomax chez les bovins.
 Certains applicateurs peuvent être incompatibles avec cette préparation.





7895000

Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Desophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies
Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Recommended Dose: 1 mL (5 mg doramectin) per 22 lb (10 kg) of body weight administered by the topical route.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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 pre-ruminating calves. Do not use in calves to be processed for veal.

Precaution: For topical use in cattle only.

Store Below 30°C (86°F)

Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.

DECTOMAX[®]
(doramectin)



Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Net Contents: 5 liters

NADA #141-095, Approved by FDA

TAKE TIME



REVERSE LABEL
DIRECTIONS



Distributed by

Animal Health

Exton, PA 19341, USA
Div of Pfizer Inc
NY, NY 10017



05-5275-00-X10
Made in USA

7895000

DECTOMAX[®] (doramectin)



Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

Treats 200 550-lb cattle

Net Contents: 5 liters

NADA #141-095, Approved by FDA

Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:

Body Weight (lb)	Dose (mL)
Up to 110	5 mL*
111-220	10 mL
221-330	15 mL
331-440	20 mL
441-550	25 mL
551-660	30 mL
661-770	35 mL
771-880	40 mL
881-990	45 mL
991-1100	50 mL

* Administer using an appropriate dosing gun.

For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1-110 lb of body weight.



Indications: For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. See package insert for complete indications and directions for use.

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora*, *Dictyocaulus viviparus*, *Ostertagia ostertagi*, *Oesophagostomum radiatum* for 28 days, and *Cooperia punctata*, *Haemonchus placei* for 35 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

Warning: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition.

Dectomax 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, rubber 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. Wash hands after use. Do not smoke or eat while handling the product.

Residue Warning: Cattle must not be slaughtered for human consumption within 45 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 prurminating calves. Do not use in calves to be processed for veal.

Precautions: This product is to be applied to skin surface only. Do not administer orally or parenterally. Do not apply to areas of skin which are caked with mud or manure.

Use Conditions: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

Store Below 30°C (86°F)

Protect From Light

Disposal: Do not contaminate water by direct application or by improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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

Not for human use

Restricted Drug (CA) Use only as directed.



Distributed by:

Animal Health

Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

15-5275-00-X10
Made in USA

DECTOMAX[®]
POUR-ON

Connect the pour-on applicator to the backpack as follows:

Attach the open end of the draw-off tubing to the pour-on applicator.

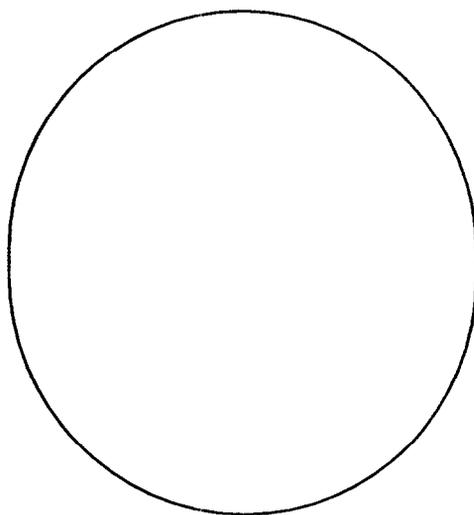
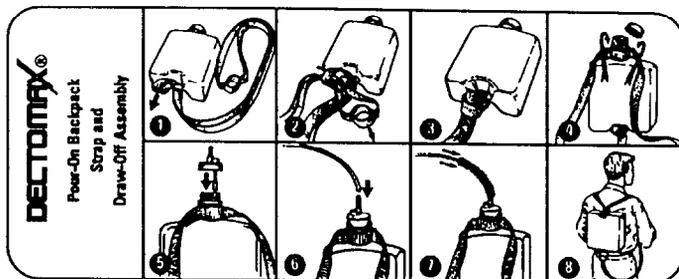
Attach draw-off tubing to the cap with the stem. Replace shipping cap with the cap that has the draw-off tubing. Tighten the draw-off cap.

Gently prime the pour-on applicator, checking for leaks (see insert).

Follow manufacturer's directions for correct use and care of the equipment.

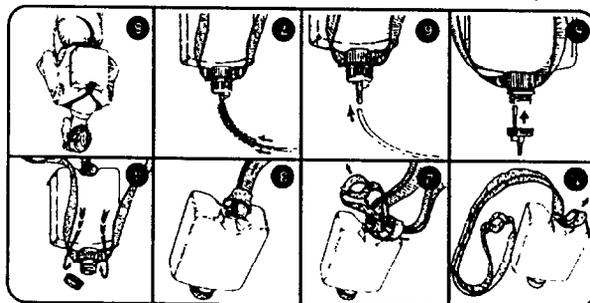
Applicators compatible with this formulation are available for use with Dectomax Pour-On for cattle.

Some applicators may be incompatible with this formulation.



997 10-5275-00-4

Joindre l'applicateur pour la solution à verser à l'applicateur à dos comme suit
Fixer l'extrémité ouverte du tuyau de vidange à l'applicateur pour la solution à verser
capuchon lié au tuyau de vidange. Serrer le capuchon avec la tige. Remplacer le capuchon d'expédition avec le
capuchon lié au tuyau de vidange au capuchon avec la tige. Remplacer le capuchon d'expédition avec le
Amorcer délicatement l'applicateur, et s'assurer qu'il n'y a aucune fuite (voir le dépliant).
Suivre les indications du fabricant concernant le mode d'emploi et l'entretien de l'équipement.
Des applicateurs compatibles avec cette préparation sont disponibles pour utilisation avec la
solution à verser Dectomax chez les bovins.
Certains applicateurs peuvent être incompatibles avec cette préparation



DECTOMAX®

(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/ml

PRODUCT DESCRIPTION: Dectomax Pour-On solution is a ready-to-use, systemically active, clear, light blue solution containing 0.5% w/v doramectin (5 mg/ml). It is formulated to deliver the recommended dosage of 500 mcg/kg (227 mcg/lb) of body weight when given by topical administration at the rate of 1 mL/22 lb (10 kg) of body weight.

PRODUCT CHARACTERISTICS: Dectomax Pour-On solution is a highly active, broad-spectrum parasiticide for topical administration to cattle. It contains doramectin, a novel tetracycline-derived macrocyclic lactone discovered by Pfizer Inc. 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 Dectomax Pour-On solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle. Studies have demonstrated the safety margin of doramectin. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose of Dectomax injectable solution. A study using Dectomax injectable solution also demonstrated safety in neonatal calves treated with up to 3 times the recommended dose. In breeding animals (bulls and cows during folliculogenesis, organogenesis, implantation, and through gestation), a dose 3 times the recommended dose of Dectomax injectable solution had no effect on breeding performance. A pharmacokinetic study demonstrated that systemic exposure to doramectin from Dectomax Pour-On was less than systemic exposure to doramectin from Dectomax injectable solution.

PRODUCT INDICATIONS: Dectomax Pour-On solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eye-worms, grubs (see PRECAUTIONS), biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal roundworms

Ostertagia ostertagi (adults and L4, including inhibited larvae)

O. lyrata (adults)

Haemonchus placei (adults and L4)

Trichostrongylus axei (adults and L4)

T. colubriformis (adults and L4)

Cooperia oncophora (adults and L4)

C. punctata (adults)

C. punctata (adults and L4)

C. sumneri (adults)

Bunostomum phlebotomum (adults)

Oesophagostomum radiatum (adults and L4)

Trichostrongylus axei (adults)

ADMINISTRATION: Dectomax Pour-On solution should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead (Dosing Cup (250-mL and 1-L bottles)).

A dosing cup is provided for use with Dectomax Pour-On solution supplied in 250-mL and 1-L bottles. The Dectomax Pour-On solution dosing cup should be installed by rotating the cup on the bottle neck until both are installed correctly. The spout is aligned at the mid-point on the wide side of the bottle.

The curved end of the dosing cup tube should be positioned at the bottom of the bottle on the side opposite the spout. When the dosing cup is in the closed position ("zero" at set dosage mark on screw), product does not enter the cup reservoir. Select a dose [1 mL per 22 lb (10 kg) of body weight] by twisting the dosing screw on the top of the dosing cup to the desired position. The first complete turn of the dosing screw will set the dose at 10 mL ("10" shows on the screw at set dose mark). Each additional turn increases the dose in 5 mL increments until a maximum dose of 50 mL ("50" is the bottom number showing on screw at the set dose mark) is reached. When body weight is between weight markings on the dosing cup, use the higher dose volume.

To fill the dosing reservoir, hold the bottle upright and squeeze it until a slight excess has been delivered as indicated by the calibration lines. Release the pressure and excess will automatically drain from the reservoir and return to the bottle.

Tilt the bottle to deliver the dose. Dectomax Pour-On solution should be delivered to cattle on the back in a single pass from the withers to the tailhead.

Applicators (2.5-L and 5-L bottles)

Applicators are available for use with Dectomax Pour-On solution supplied in 2.5- and 5-L backpacks. Directions for 2 recommended applicators are provided below. Some applicators may be incompatible with this formulation.

Phillips Pour-On Applicator System

1. Replace the shipping cap on 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring counter clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose to maximum (50 mL). Gently prime the applicator, checking for leaks. To prime, place the nozzle into a clean, dry receptacle and depress lever fully. Pump 3-4 short strokes ensuring that the piston reaches the end of the cylinder, and then release the lever completely to fill the cylinder. A small air bubble may appear within the cylinder. This will not affect the dosing accuracy.
5. Set the required dose and administer:
 - a) Set backpack in upward position.
 - b) Discharge residual material from the applicator and draw off tubing into a separate, clean, dry receptacle.

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7. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.

8. Remove the draw-off cap. Replace with the original cap and tighten firmly.

Sprayer Pour-On Applicator System

1. Replace the shipping cap on the 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring counter clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose at the maximum (50 mL) by unscrewing the adjuster at the base of the handle. Gently prime the applicator, checking for leaks. To prime, point the nozzle into a clean, dry receptacle and gently pump the lever back and forth to expel air from the system. When the barrel completely fills after every priming stroke, set the dose.
5. Set the dose as follows:

- a) Use the handle to align the middle of the blue plunger ring with the chosen mark on the barrel. Tighten the adjuster screw against the handle.
- b) Secure the dose with the adjuster screw locknut.

Note: Dose accuracy can be checked by dispensing a known number of set doses into a measuring cylinder. Correct any inaccuracy by adjusting the dose setting screw. Repeat this procedure until desired accuracy is achieved.

6. Administer each dose by fully depressing the handle so that the plunger travels its entire length. Release the handle and the applicator will automatically refill.
7. To disconnect the system proceed as follows:

- a) Set backpack in upward position.
- b) Discharge residual material from the applicator and draw off tubing into a separate, dry receptacle.

8. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.

9. Remove the draw-off cap. Replace with the original cap and tighten firmly.

DIRECTIONS FOR USE OF APPLICATOR SYSTEM FOR 22-L CONTAINER

1. Attach internal tube to internal tube barb on draw-off cap provided.
2. Remove shipping cap from container and replace with draw-off cap.
3. Place the external draw-off hose onto the external hose barb, positioned on the outside (top) of the draw-off cap. Screw the anti-kink spring over the hose and hose barb.
4. Attach the other end of the hose to the hose barb on the pour-on applicator. Screw the anti-kink spring over the hose and pour-on applicator.
5. Set the applicator to the maximum dose. Prime the applicator. Check for leaks, or any air bubbles entering the hose. Place the nozzle of the applicator into a clean, dry receptacle and depress finger grip; pump these grips until the cylinder is full of product and the air is removed. A small bubble may appear in the cylinder. This will not affect dosing accuracy.
6. Select the desired dose and administer product.
7. To disconnect the system, proceed as follows:
 - a) Carefully unscrew the breather cap from the container. Lift the internal draw tube until it is clear of the Dectomax Pour-On in the 22-L container.
 - b) Place the nozzle of the pour-on back into the 22-L container and squeeze the finger grips until all product is removed from the tube and applicator.
 - c) Replace original shipping cap onto the 22-L container.
8. Follow manufacturer's recommendation for care and

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 Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, or obtain more information, or to obtain an MSDS, call 1-800-366-5288.

Dectomax 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, rubber 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.

RESIDUE WARNING: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 30 months of age or older. A withdrawal period has not been established for this product in pregnant calves. Do not use in calves to be processed for veal.

PRECAUTIONS

Dectomax Pour-On solution has been developed specifically for use in cattle only. This product should not be used in other animal species as adverse reactions, including fatalities in dogs, may result.

This product is to be applied to skin surface only. Do not administer orally or parenterally.

Do not apply to areas of skin which are caked with mud or manure.

Wash hands after use.

Do not smoke or eat while handling the product.

Cloudiness in the formulation may occur when Dectomax Pour-On solution is stored at temperatures below 0°C (32°F). Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

Dectomax Pour-On solution is highly effective against 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 gutlet may cause blood killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Dectomax Pour-On solution, but can occur with any successful treatment of grubs. Cattle should be treated either before or after the migratory phase of grub development. Consult your veterinarian concerning the proper time for treatment. Cattle treated with Dectomax Pour-On solution after the end of heel fly season may be re-treated with Dectomax Pour-On during the winter for internal parasites, mange mites, or biting and sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

USE CONDITIONS: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

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 cattle to enter lakes, streams or ponds for at least 6 hours after treatment. 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.

Store Below 38°C (96°F)

Protect From Light

HOW SUPPLIED: Dectomax Pour-On solution is available in 250-mL, 1-L, 2.5-L, 5-L, and 22-L multi-dose containers.

NADA #141-095, Approved by FDA

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

Not for human use.

Restricted Drug (CA) Use only as directed.

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