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JUN 18 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-099

CYDECTIN® (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle

This supplemental NADA FOI Summary contains 10 new label indications for adult or L₄ stages of gastrointestinal roundworms and for 2 additional persistent activity indications.

Sponsored by

Fort Dodge Animal Health

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NADA 141-099

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I. GENERAL INFORMATION

NADA Number: 141-099

Sponsor: Fort Dodge Animal Health
800 Fifth St. NW
Fort Dodge, Iowa 50501

Established Name: moxidectin

Tradename: CYDECTIN® (moxidectin) 0.5% Pour-On
for Beef and Dairy Cattle

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: New indications for the gastrointestinal roundworms
appearing in bold print in Section II and new persistent
activity indications of 14 days for *Haemonchus placei*
and 28 days for *Oesophagostomum radiatum*.

II. INDICATIONS FOR USE: Effective in the treatment and control of the
following internal and external parasites. New indications appear in bold print.

Gastrointestinal Roundworms

Ostertagia ostertagi - Adult and fourth-stage larvae (including inhibited larvae)
Haemonchus placei - Adult and **fourth-stage larvae**
Trichostrongylus axei - Adult and fourth-stage larvae
Trichostrongylus colubriformis - Adult and **fourth-stage larvae**
Cooperia oncophora - Adult and **fourth-stage larvae**
Cooperia pectinata - **Adult**
Cooperia punctata - Adult and **fourth-stage larvae**
Cooperia spatulata - **Adult**
Cooperia surnabada - **Adult and fourth-stage larvae**
Bunostomum phlebotomum - Adult
Oesophagostomum radiatum - Adult and **fourth-stage larvae**
Nematodirus helvetianus - Adult and **fourth-stage larvae**

Lungworms

Dictyocaulus viviparus - Adult and fourth-stage larvae

Cattle Grubs

Hypoderma bovis
Hypoderma lineatum

Mites

Chorioptes bovis

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

Lice

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

Bovicola (*Damalinia*) *bovis*

Horn Flies

Haematobia irritans

CYDECTIN Pour-On has been proven to effectively control infections and protect from reinfection with *Haemonchus placei* for 14 days after treatment, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days after treatment, and *Dictyocaulus viviparus* for 42 days after treatment.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

- A. Form: CYDECTIN (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle is a ready-to-use topical formulation that contains 5 mg moxidectin per mL of solution.
- B. Route of Administration: The product should be applied directly to the hair and skin along the top of the back from the withers to the base of the tail. Application should be made to healthy skin avoiding mange scabs, skin lesions or extraneous foreign matter.
- C. Recommended Dose Rate: The recommended rate of administration is 1 mL for each 22 lb (10 kg) of body weight which provides 5 mg moxidectin for each 22 lb (10 kg) of body weight.

IV. EFFECTIVENESS

Effectiveness studies were presented in the original NADA 141-099 FOI Summary dated January 28, 1998 establishing the recommended effective dose of Cydectin Pour-On for the control of a broad spectrum of ecto- and endoparasites as label indications, and periods of persistent effect against *Ostertagia ostertagi* and *Dictyoaulus viviparus*. This summary contains the results of studies conducted to confirm the effectiveness of the recommended dose of 0.5 mg moxidectin/kg body weight against additional species and life stages of nematodes as new therapeutic claims. It also contains the results of studies conducted to determine the period of persistent activity for additional nematode species.

Effectiveness of moxidectin pour-on against parasites was calculated as the reduction in the number of a specific stage and species of parasite in treated animals as compared to the number in vehicle or untreated control animals. Percent effectiveness was calculated using geometric means in the following formula.

$$= \left(\frac{\text{mean parasite count in control group} - \text{mean parasite count in treated group}}{\text{mean parasite count control group}} \right) \times 100$$

The statistical analysis was performed separately for each species and stage of nematode, as appropriate. Statistical analysis was performed for a nematode species only if at least six animals in the control group were infected with that specific parasite. Counts were transformed by a $Y = \log_{10}(\text{count} + 1)$ transformation before performing a one-way Analysis of Variance (ANOVA) with treatment in the model. The treatment effect was tested against the residual error in the ANOVA for significance at the 5% level. The least square means (LSMEAN) was calculated for each group and the moxidectin-treated group was compared to the control group at the 5% level of significance (one-sided). The Dunnett t-test was used for comparisons when studies contained several moxidectin treatment groups compared to a single control group (e.g., persistent activity studies).

In order for an individual study to be considered an acceptable demonstration of the therapeutic or persistent activity of moxidectin pour-on against a specific parasite, the following criteria were applied.

- a) at least six control animals were adequately infected with the specific parasite species/stage;
- b) treatment with the recommended dose resulted in at least a 90% reduction in the parasite count as compared to controls; and
- c) the reduction was significant at $P < 0.05$.

For each claim that was granted there were at least 2 studies with an adequate level of infection that met the 3 criteria above.

Persistent Effectiveness against Gastrointestinal Roundworms

The persistent activity of Cydectin Pour-On against gastrointestinal roundworms was evaluated in three studies. Two of these studies also contained a treatment group that was designed to evaluate effectiveness against existing infections of fourth-stage larvae.

Persistent Effectiveness Studies

Study Number 0863-B-US-19-97

1. Title: Evaluation of the persistent activity of moxidectin 0.5% pour-on against *Haemonchus placei*, *Trichostrongylus axei* and *Nematodirus helvetianus* (Louisiana).
2. Investigator: James C. Williams, Ph.D.
Louisiana State University
Baton Rouge, LA
3. General Design:
 - a. Purpose: This study was designed to determine the time period following treatment in which reinfections with certain gastrointestinal roundworms in cattle are prevented.
 - b. Animals: Forty Holstein calves weighing between 139 to 244 kg, were assigned to the five treatment groups (8 animals per group) in a completely random fashion. With the exception of one heifer calf, all animals were either bulls or steers. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
 - c. Housing: Calves were maintained in outdoor concrete-floored pens by treatment group and exposed to ambient weather conditions.
 - d. Infection: On Day 0, each calf was infected with an inoculating dose of L₃ larvae containing approximately 7,996 *Haemonchus placei*, 11,655 *Trichostrongylus axei*, 3,666 *Nematodirus helvetianus*, 2,732 *Cooperia* spp., 3,470 *Ostertagia ostertagi*, and 2,635 *Oesophagostomum radiatum*.
 - e. Procedure: To evaluate persistent activity, a different group of cattle were treated with moxidectin pour-on at 35, 28, 21, and 14 days prior to an experimental infection, with the fifth group remaining as untreated

controls. Equal numbers of cattle from each treatment group were necropsied 21 to 23 days postinfection.

- f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for parasites present in a minimum of six adequately infected control calves are given in the Table 4.1.

Table 4.1 Geometric mean of control worm counts and percent effectiveness

Nematode	Untreated Control Mean	% Effectiveness of Moxidectin at various Pre-infection Treatment Days ¹			
		-35	-28	-21	-14
<i>H. placei</i>	890.7	0	29.9	44.9	99.2
<i>O. ostertagi</i>	1140.4	0	0	8.1	77.7
<i>T. axei</i>	383.6	0	0	0	0
<i>N. helvetianus</i>	867.7	0	0	0	0
<i>Oe. radiatum</i>	716.9	77.9	99.0	98.9	100

¹Treatment group indicates the day cattle were treated with moxidectin relative to the day they were administered an experimental infection.

5. Conclusion: This study demonstrated that Cydectin Pour-On had persistent activity for 14 days against *H. placei* and for 28 days against *Oe. radiatum*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0863-B-US-20-97

1. Title: Evaluation of the efficacy of moxidectin against fourth-stage larvae and the persistent activity of moxidectin 0.5% pour-on against *Haemonchus placei*, *Trichostrongylus axei*, and *Nematodirus helvetianus* (Arkansas).
2. Investigator: Thomas A. Yazwinski, Ph.D.
University of Arkansas
Fayetteville, AR
3. General Design:
- a. Purpose: This study was designed to determine the time period following treatment in which reinfections with certain gastrointestinal roundworms in cattle are prevented and to determine effectiveness against L₄ stage infections present at the time of treatment.

- b. **Animals:** Forty-eight Holstein steer calves weighing between 73 and 175 kg, were assigned to the six treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
- c. **Housing:** Calves were maintained in outdoor concrete-floored pens by treatment group and exposed to ambient weather conditions.
- d. **Infection:** On Day 0, each calf was infected with an inoculating dose of L₃ larvae containing approximately 4,385 *Haemonchus placei*, 4,827 *Oesophagostomum radiatum*, 673 *Cooperia* spp., 6,442 *Trichostrongylus axei*, and 3,135 *Nematodirus helvetianus*. Additionally, animals received 1,077 *Trichuris* spp. eggs.
- e. **Procedure:** To evaluate persistent activity, a different group of cattle was treated with moxidectin pour-on at 35, 28, 21, and 14 days prior to an experimental infection. One group was treated 6 days postinfection to evaluate effectiveness against an existing infection of L₄ larvae. The final treatment group contained untreated control animals. Equal numbers of cattle from each treatment group were necropsied 20 to 24 days postinfection.
- f. **Primary Variable:** Nematodes collected at necropsy were counted and identified.
4. **Results:** Effectiveness data for parasites present in a minimum of six adequately infected control calves are given in Table 4.2.

Table 4.2 Geometric mean of control worm counts and percent effectiveness

Nematode	Untreated Control Geo mean	% Efficacy of Moxidectin at various Pre-infection Treatment Days ¹				
		-35	-28	-21	-14	Day 6 L ₄
<i>H. placei</i>	199.5	72.7	34.9	94.3	99.6	100
<i>O. ostertagi</i>	4724.8	25.4	23.7	84.4	98.4	>99.9
<i>T. axei</i>	542.6	12.0	26.7	38.9	89.4	100
<i>N. helvetianus</i>	533.7	31.2	14.2	59.3	0	99.9
<i>Oe. radiatum</i>	1137.0	79.6	97.9	99.3	99.7	>99.9

¹Treatment group indicates the day cattle were treated with moxidectin relative to the day they were administered an experimental infection.

5. **Conclusion:** This study demonstrated that Cydectin Pour-On had persistent activity for 21 days against *H. placei* and 28 days persistent activity against *Oe. radiatum*. It was also demonstrated to be effective against the L₄ stage of *H. placei*, *O. ostertagi*, *N. helvetianus*, *T. axei*, and *Oe. radiatum*.

6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0863-B-US-25-98

1. Title: Evaluation of the efficacy of moxidectin 0.5% pour-on against fourth-stage larvae and the persistent activity against *Haemonchus placei*, *Trichostrongylus axei* and *Nematodirus helvetianus* conducted in New Jersey.
2. Investigator: Siva Ranjan, B.V.Sc., Ph.D.
Fort Dodge Animal Health
Princeton, NJ
3. General Design:
 - a. Purpose: This study was designed to determine the time period following treatment in which reinfections with certain gastrointestinal roundworms in cattle are prevented and to determine effectiveness against L₄ stage infections present at the time of treatment.
 - b. Animals: Forty-eight Holstein steer calves weighing between 74 and 133 kg, were assigned to the six treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
 - c. Housing: Calves were maintained in indoor concrete-floored pens by treatment group (4 animals/pen).
 - d. Infection: On Day 0, each calf was infected with an inoculating dose of L₃ larvae containing approximately 10,000 *Haemonchus placei*, 5,000 *Trichostrongylus axei*, and 3,000 *Nematodirus helvetianus*. Additionally, the inoculum contained *Ostertagia* spp., *Cooperia* spp., and *Oesophagostomum radiatum*.
 - e. Procedure: To evaluate persistent activity, a different group of cattle were treated with moxidectin pour-on at 35, 28, 21, and 14 days prior to an experimental infection. One group was treated 6 days postinfection to evaluate effectiveness against an existing infection of L₄ larvae. The final treatment group contained untreated control animals. Equal numbers of cattle from each treatment group were necropsied 20 to 23 days postinfection.

- f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for parasites present in a minimum of six adequately infected control calves are given in Table 4.3.

Table 4.3 Geometric mean of control worm counts and percent effectiveness

Nematode	Untreated Control Geo mean	% Effectiveness of Moxidectin at various Pre-infection Treatment Days ¹				
		-35	-28	-21	-14	Day 6 L ₄
<i>H. placei</i>	1087.1	14.1	99.6	97.1	98.9	100
<i>O. ostertagi</i>	3022.9	0	98.0	96.7	98.7	100
<i>T. axei</i>	466.0	43.1	92.8	93.9	97.9	100
<i>N. helvetianus</i>	1798.1	0	34.1	44.9	31.3	99.7
<i>Oe. radiatum</i>	1190.0	72.2	100	99.9	99.9	100

¹Treatment group indicates the day cattle were treated with moxidectin relative to the day they were administered an experimental infection.

5. Conclusion: This study demonstrated that Cydectin Pour-On had persistent activity for 28 days against *H. placei* and *Oe. radiatum*. It was also demonstrated to be effective against the L₄ stage of *H. placei*, *N. helvetianus*, *T. axei*, *O. ostertagi*, and *Oe. radiatum*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Dose Confirmation Studies

Study Number 0863-B-US-21-97

1. Title: Dose confirmation of moxidectin 0.5% pour-on against adult and fourth-stage larvae of various *Cooperia* spp. and *Trichostrongylus colubriformis* (Louisiana).
2. Investigator: James C. Williams, Ph.D.
Louisiana State University
Baton Rouge, LA
3. General Design:
 - a. Purpose: To confirm effectiveness against a variety of adult and fourth-stage larvae of gastrointestinal nematodes.

- b. Animals: Thirty two Holstein steers weighing between 112 and 241 kg were assigned to the four treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
- c. Housing: Cattle were maintained in outdoor concrete-floored pens by treatment group and exposed to ambient weather conditions.
- d. Infection: On Day 0, each calf was infected with an inoculating dose containing the following approximate numbers of L₃ larvae: 34,965 *C. punctata*, *C. pectinata*, *C. spatulata*, and *C. surnabada*; 5,996 *C. oncophora/surnabada*, 1,550 *Ostertagia ostertagi*, and 4,996 *T. colubriformis*.
- e. Procedure: One group of calves was treated on Day 6 postinfection to evaluate effectiveness against the L₄ stage of the nematodes and the other group was treated on Day 23 postinfection to evaluate effectiveness against adult nematodes. There was a corresponding untreated control group for each moxidectin pour-on group. All cattle were experimentally infected on Day 0 of the study. Necropsies were performed on Days 20 and 21 postinfection for one control group and for cattle treated with moxidectin on Day 6. Cattle treated on Day 23 postinfection and their untreated control group were necropsied on Days 37 and 38.
- f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for parasites present in a minimum of six adequately infected control calves are given in Table 4.4.

Table 4.4 Geometric mean of control worm counts and percent effectiveness

Nematode species	Geometric Mean Control Cattle	% Effectiveness of Moxidectin Pour-On
<i>C. oncophora</i> Adult	787.2	99.9
<i>C. punctata</i> Adult	6545.9	99.9
<i>C. spatulata</i> Adult	116.5	99.3
<i>C. surnabada</i> Adult	276.9	99.7
<i>T. colubriformis</i> Adult	149.3	100
<i>C. punctata</i> L ₄	1599.6	99.7

5. Conclusion: This study demonstrated that moxidectin pour-on was effective against the adult stage of *C. oncophora*, *C. punctata*, *C. spatulata*, *C. surnabada*, and *T. colubriformis* and against the L₄ stage of *C. punctata*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0863-B-US-26-98

1. Title: Dose confirmation study with 0.5% moxidectin pour-on and 1% nonaqueous injectable formulations against adult and L₄ stages of various *Cooperia* species, *Trichostrongylus colubriformis*, and L₄ stages of *Dictyocaulus viviparus* in cattle conducted in New Jersey.
2. Investigator: Siva Ranjan, B.V.Sc., Ph.D.
Fort Dodge Animal Health
Princeton, NJ
3. General Design:
 - a. Purpose: To confirm effectiveness against a variety of adult and fourth-stage larvae of gastrointestinal nematodes.
 - b. Animals: Forty-eight Holstein steers weighing between 112 and 172 kg were assigned to six treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
 - c. Housing: Calves were maintained in indoor concrete-floored pens by treatment group (4 animals/pen).
 - d. Infection: On Day 0, each calf was infected with an inoculating dose containing approximately 30,000 *Cooperia* spp., 10,000 *T. colubriformis*, and 1,500 *Dictyocaulus viviparus* L₃ larvae.
 - e. Procedure: One group of calves was treated on Day 5 postinfection to evaluate effectiveness against the L₄ stage of the nematodes and the other group was treated on Day 26 postinfection to evaluate effectiveness against adult nematodes. There was a corresponding untreated control group for each moxidectin pour-on group. The two remaining groups were not relevant to this NADA and data from these animals are not presented. Necropsies were performed on Days 24 and 25 postinfection for one control group and for cattle treated with

moxidectin on Day 5. Cattle treated on Day 26 postinfection and their untreated control group were necropsied on Days 40 and 41.

- f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for the 0.5% pour-on for parasites present in a minimum of six adequately infected control calves are given in Table 4.5.

Table 4.5 Geometric mean of control worm counts and percent effectiveness

Nematode species	Geometric Mean in Control Cattle	% Efficacy of Moxidectin Pour-On
L₄ Larvae		
<i>Dictyocaulus viviparus</i>	47.0	100
<i>Cooperia oncophora</i>	1252.7	99.8
<i>Cooperia punctata</i>	1772.7	>99.9
<i>Cooperia spatulata</i>	2247.6	>99.9
<i>Cooperia surnabada</i>	1266.2	99.9
<i>Trichostrongylus colubriformis</i>	618.5	100
Adults		
<i>Cooperia oncophora</i>	501.9	98.0
<i>Cooperia spatulata</i>	1608.6	>99.9
<i>Cooperia punctata</i>	1067.5	100
<i>Cooperia surnabada</i>	409.3	99.3
<i>Trichostrongylus colubriformis</i>	77.6	99.4

5. Conclusion: This study demonstrated that moxidectin pour-on was effective against adult and L₄ stages of *C. oncophora*, *C. punctata*, *C. spatulata*, *C. surnabada*, and *T. colubriformis*. It was also effective against the L₄ stage of *D. viviparus*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0693-B-US-30-98

1. Title: Dose confirmation study of 1% nonaqueous injectable and 0.5% moxidectin pour-on against adult and L₄ stages of various *Cooperia* species and *Trichostrongylus colubriformis* (Idaho).
2. Investigator: Edward Johnson, DVM Gary Zimmerman DVM, Ph.D.
 Johnson Research Zimmerman Research
 Parma, ID Livingston, MT

3. General Design:

- a. Purpose: To confirm effectiveness against a variety of adult and fourth-stage larvae of gastrointestinal nematodes.
 - b. Animals: Forty-eight Holstein steers weighing between 156 and 245 kg, were assigned to six treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
 - c. Housing: Calves were maintained in dirt-floored pens by treatment group.
 - d. Infection: On Day 0, each calf was infected with an inoculating dose of L_3 larvae containing approximately 5,000 *C. oncophora*/*C. surnabada*, 15,000 *C. punctata*/*C. pectinata*/*C. spatulata*/*C. surnabada*; and 15,000 *T. colubriformis*.
 - e. Procedure: One group of calves was treated on Day 6 postinfection to evaluate efficacy against the L_4 stage of the nematodes and the other group was treated on Day 23 postinfection to evaluate efficacy against adult nematodes. There was a corresponding untreated control group for each moxidectin pour-on group. The two remaining groups were not relevant to this NADA and data from these animals are not presented. Necropsies were performed on Days 20 postinfection for one control group and for cattle treated with moxidectin on Day 6. Cattle treated on Day 23 postinfection and their untreated control group were necropsied on Days 37.
 - f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for the 0.5% pour-on for parasites present in a minimum of six adequately infected control calves are given in Table 4.6.

Table 4.6 Geometric mean of control worm counts and percent effectiveness

Nematode species	Geometric Mean in Control Cattle	% Efficacy of Moxidectin Pour-On
L_4 Larvae		
<i>Cooperia oncophora</i>	580.6	99.6*
<i>Cooperia pectinata</i>	525.0	99.8*

<i>Cooperia punctata</i>	2645.6	99.8*
<i>Cooperia surnabada</i>	258.9	99.3*
<i>Trichostrongylus colubriformis</i>	485.8	100.0*

Adults

<i>Cooperia pectinata</i>	145.3	99.5*
<i>Cooperia surnabada</i>	144.4	96.7*

*Nematode counts for moxidectin-treated cattle were less than those from the controls at $P < 0.05$ (log transformed counts were analyzed).

5. Conclusion: This study demonstrated that moxidectin pour-on was effective against the L₄ stage of *C. oncophora*, *C. pectinata*, *C. punctata*, *C. surnabada*, and *T. colubriformis*. It was also shown to be effective against adult *C. pectinata* and *C. surnabada*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0863-B-US-22-97

1. Title: Dose confirmation study of 1% nonaqueous injectable and 0.5% moxidectin pour-on against experimentally-induced larval and adult *Bunostomum phlebotomum*, *Oesophagostomum radiatum*, and *Trichuris* spp. infections in cattle (Tennessee).
2. Investigator: Craig R. Reinemeyer, D.V.M., Ph.D.
East Tennessee Clinical Research
Knoxville, TN
3. General Design:
 - a. Purpose: To confirm effectiveness against a variety of adult and fourth-stage larvae of gastrointestinal nematodes.
 - b. Animals: Forty-eight Holstein and Holstein crossbred steers weighing between 66 and 159 kg, were assigned to six treatment groups (8 animals per group) in a completely random fashion. Cattle had been treated with an approved anthelmintic following purchase and all animals had negative fecal EPG counts at the start of the study.
 - c. Housing: Calves were maintained in outdoor concrete-floored pens by treatment group. There was a shelter over approximately 40% of the pen with the remainder being open to ambient weather conditions

- d. Infection: One moxidectin-treated and one untreated control group were used to evaluate efficacy against the L₄ stage. These groups were infected with approximately 1,000 larvated *Trichuris* spp. eggs and 640 *Oesophagostomum radiatum* and 430 *Bunostomum phlebotomum* larvae on Day -16. One moxidectin-treated and one untreated control group were used to evaluate efficacy against the adult stage. These groups were infected with approximately 1,000 larvated *Trichuris* spp. eggs on Day -63 and 2500 *Oesophagostomum radiatum* and 500 *Bunostomum phlebotomum* larvae on Day -35.
- e. Procedure: One group of calves was infected and treated in a manner such that efficacy against the L₄ stage of the nematodes could be evaluated and another group of cattle was infected and treated in a manner to determine activity against the adult stage. There was a corresponding untreated control group for each moxidectin pour-on group. The two remaining groups were not relevant to this NADA and data from these animals are not presented. All cattle were necropsied on Days 14 through 16 posttreatment.
- f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for the 0.5% pour-on for parasites present in a minimum of six adequately infected control calves are given in Table 4.7.

Table 4.7 Geometric mean of control worm counts and percent effectiveness

Nematode species	Geometric Mean in Control Cattle	% Efficacy of Moxidectin Pour-On
L₄ Larvae		
<i>Oesophagostomum radiatum</i>	92.7	100*
<i>Trichuris</i> spp.	135.2	99.2*
Adults		
<i>Oesophagostomum radiatum</i>	283.3	100*
<i>Trichuris</i> spp.	120.9	99.8*

*Nematode counts for moxidectin-treated cattle were less than those from the controls at P<0.05 (log transformed counts were analyzed).

5. Conclusion: This study demonstrated that moxidectin pour-on was effective against adult and L₄ stages of *Trichuris* spp. and *Oesophagostomum radiatum*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number 0693-B-US-20-98

1. Title: Dose confirmation study of 1% nonaqueous injectable and 0.5% moxidectin pour-on against both naturally-acquired and experimentally-induced L4 nematode infections in cattle, with emphasis on *Bunostomum phlebotomum* and *Oesophagostomum radiatum* (Kentucky).
2. Investigator: Gil Meyers, Ph.D.
Gil Meyers, Ph.D., Inc.
Magnolia, Kentucky
3. General Design:
 - a. Purpose: To confirm effectiveness against a variety of fourth-stage larvae of gastrointestinal nematodes.
 - b. Animals: Thirty crossbred beef steers, weighing between 163 and 329 kg, were randomly assigned to three treatment groups (10 animals per group).
 - c. Housing: Cattle were maintained together on a common pasture until the treatment day after which they were maintained in separate pastures by treatment group until necropsy.
 - d. Infection: Calves had naturally-acquired *Bunostomum phlebotomum* and *Oesophagostomum radiatum* infections. All calves were also administered an experimental infection of 1,000 *Bunostomum* and 1,000 *Oesophagostomum* L₃ larvae on Day -15 relative to treatment. The experimental infections were used to evaluate efficacy of moxidectin pour-on against the L₄ stage of these nematodes.
 - e. Procedure: One group of calves was treated with moxidectin pour-on on Day 0, and one group was untreated control animals. The third group was not relevant to this NADA and data from these animals are not presented. Necropsies were performed on Days 14 to 17 posttreatment.
 - f. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for the 0.5% pour-on for parasites present in a minimum of six adequately infected control calves are given in Table 4.8.

Table 4.8 Geometric mean of control worm counts and percent effectiveness

Nematode species and stage	Geometric Mean in Control Cattle	% Efficacy of Moxidectin
<i>Oesophagostomum radiatum</i> , L ₄	48.3	100*
<i>Oesophagostomum radiatum</i> , adults	129.6	100*

*Nematode counts for moxidectin-treated cattle were less than those from the controls at $P < 0.05$ (log transformed counts were analyzed).

5. Conclusion: This study demonstrated that moxidectin pour-on was effective against the adult and L₄ stage of *Oesophagostomum radiatum*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Study Number B-92-14

1. Type of Study: Dose confirmation study in cattle with naturally-acquired gastrointestinal roundworm infections and induced infections of hookworm and lungworm.
2. Investigator: J.C. Williams, Ph.D.
Louisiana State University
Baton Rouge, LA
3. General Design:
 - a. Purpose: This study was designed to confirm the effective dose for the control of nematode infections in cattle.
 - b. Animals: Twenty mixed beef breed heifers, weighing between 122 and 184 kg, were ranked by pretreatment fecal lungworm larval counts, paired and randomly assigned to either the moxidectin pour-on treated group or the control group.
 - c. Housing: Animals were maintained in outdoor pens with concrete floors by treatment group and exposed to ambient weather conditions.
 - d. Infection: Cattle were infected with approximately 2,316 hookworm L₃ larvae on Day -77. On Day -29, cattle were infected with approximately 1,509 third-stage hookworm larvae and 1,080 third-stage lungworm larvae. These experimentally-induced infections were superimposed over naturally-acquired nematode infections.

-
- e. Controls: Pour-on vehicle (no moxidectin) was applied once to calves at 1 mL/10 kg body weight providing 0 mg moxidectin/kg body weight.
- f. Procedure: Cattle were treated on Day 0. Necropsy was on Day 14 or 15 post-treatment.
- g. Primary Variable: Nematodes collected at necropsy were counted and identified.
4. Results: Effectiveness data for the 0.5% pour-on for parasites present in a minimum of six adequately infected control calves are given in Table 4.9.

Table 4.9 Geometric mean of control worm counts and percent effectiveness

Nematode species and stage	Geometric Mean in Control Cattle	% Efficacy of Moxidectin Pour-on 0.5 mg/kg
<i>Cooperia pectinata</i> , male adult	26	100
<i>Cooperia spatulata</i> , male adult	62	100

5. Conclusions: This study demonstrated that moxidectin pour-on was effective against the adult stage of *Cooperia pectinata* and *Cooperia spatulata*.
6. Adverse Reactions: No adverse reactions to treatment were observed.

Persistent effect of CYDECTIN against *Ostertagia ostertagi* was demonstrated to be 28 days in studies conducted for the original approval. Two of three studies conducted for this supplement failed to support persistent activity for 28 days. The following table gives a summary of results for all studies demonstrating the persistent effect of CYDECTIN against *Ostertagia ostertagi*. An advisory statement has been added to the labeling that effectiveness was less than 90% in some field studies.

TABLE 4.10 SUMMARY OF PERSISTENT ACTIVITY AGAINST *OSTERTAGIA OSTERTAGI*

0863 PERSISTENCE TRIALS - OVERSEAS

Study #	UK-03-92	AU-04-92	BE-10-94	BE-13-95	FR-13-93	FR-14-94	NZ-09-92
Year	1992	1992	1994	1995	1993	1994	1992
Site	Scotland	Australia	Belgium	Belgium	France	France	N.Z.
Geo Mean Control	13,826	3,453	26,104	15,503	18,078	28,508	1,113
Eff Day 28	99.1%	99.7%	96.6%	97.9%	86.9%	99.9%	99.2%
Eff Day 21	>99.9%	>99.9%			99.9%	99.9%	99.2%
Eff Day 14	99.1%	>99.9%			99.9%	>99.9%	

0863 PERSISTENCE TRIALS - U.S.

Study #	US-5-95	US-6-95	US-8-96	US-19-97	US-20-97	US-25-98
Year	1996	1996	1996	1998	1998	1998
Site	N. Carolina	Idaho	N.J.	Louisiana	Arkansas	N.J.
Geo Mean Control	1,031	5,072.3	3,480.3	835.4	2,335.3	1,724.5
Eff Day 28	98.9%	100%	99.8%	0%	26.2%	97.9%
Eff Day 21	99.7%	100%	99.9%	0%	84.9%	96.0%
Eff Day 14	99.1%	>99.9%		93.5%	98.5%	98.7%

V. TARGET ANIMAL SAFETY

Target animal safety data were presented in the original NADA 141-099 FOI Summary dated January 28, 1998. No additional data were required for approval of this supplement.

VI. HUMAN SAFETY

All human safety information appear in the original NADA 141-099 FOI Summary dated January 28, 1998 and the supplemental FOI Summary dated November 2, 1999. No additional information was required for this supplemental approval.

VII. 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 implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) to demonstrate that CYDECTIN[®] (moxidectin) Pour-On Solution for Cattle, is safe and effective for the treatment and control of infections and infestations of certain internal and external parasites in beef and dairy cattle, when administered topically at a dose of 500 mcg/kg bodyweight.

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

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals qualifies for THREE years of marketing exclusivity beginning on the date of approval because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food

producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the new claim for which the supplemental application is approved.

CYDECTIN® (moxidectin) Pour-On Solution for Beef and Dairy Cattle is under U.S. patent number 4,916,154, which expires on April 10, 2007.

VIII. APPROVED PRODUCT LABELING

Facsimile bottle labeling, insert, and box container for the 500 mL, 1 liter, 2.5 liter, 5 liter and 10 liter size container are attached.

Copies of applicable labeling may be obtained by writing to:

Freedom of Information Office
Center for Veterinary Medicine, FDA
7500 Standish Place
Rockville, MD 20855

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1365.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN (moxidectin) Pour-On may be used for human consumption at any time following treatment. 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

For external use only. Do not apply to areas of skin with mange scabs, skin lesions, mud or manure. CYDECTIN Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for topical use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.

CYDECTIN Pour-On is effective against the migrating stage of cattle grubs (*Hypoderma* larvae). Treatment with CYDECTIN Pour-On during the period when grubs are migrating through vital areas may cause undesirable host-parasite reactions. Killing *H. lineatum* when they are located in peri-esophageal tissues may cause bloat. Killing *H. bovis* when they are in the vertebral canal may cause staggering or hindlimb paralysis. Cattle should be treated as soon as possible after heel fly (warble fly) season to avoid this potential problem. Cattle treated with CYDECTIN Pour-On at the end of fly season can be re-treated during the winter without danger of grub-related reactions. Consult your veterinarian for more information regarding these secondary grub reactions and the correct time to treat with CYDECTIN Pour-On.

ENVIRONMENTAL SAFETY

Studies indicate that when moxidectin comes in contact with the soil it readily and tightly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE

Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL

Dispose of containers in an approved landfill or by incineration.

PACKAGE INFORMATION

CYDECTIN Pour-On is available in five convenient container sizes. The 16.91 fl oz/500 mL (NDC 0856-2680-01) and 33.81 fl oz/1 L (NDC 0856-2680-02) are packaged in specially designed squeeze-measure-pour polyethylene bottles. When treating larger numbers of cattle, 84.54 fl oz/2.5 L (NDC 0856-2680-03), 169 fl oz/5 L (NDC 0856-2680-04), or 338 fl oz/10 L (NDC 0856-2680-05) conventional polyethylene containers are available for use with most commercially-available topical applicators.

U.S. Patent No. 4,916,154

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

00881

Revised March 2001

2680G

NADA 141-099, Approved by FDA

CYDECTIN® moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

For Treatment of Infections and Infestations Due to
Internal and External Parasites of Beef and Dairy Cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. If animals are likely to be reinfected following treatment, a strategic parasite control program should be established.

MODE OF ACTION

Moxidectin is an endectocide in the milbemycin chemical class which shares the distinctive mode of action characteristic of macrocyclic lactones. CYDECTIN (moxidectin) Pour-On is specially formulated to allow moxidectin to be absorbed through the skin and distributed internally to the areas of the body affected by endo- and/or ectoparasitism. Moxidectin binds selectively and with high affinity to glutamate-gated chloride ion channels which are critical to the function of invertebrate nerve and muscle cells. This interferes with neurotransmission resulting in paralysis and elimination of the parasite.

INDICATIONS

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

Gastrointestinal Roundworms

Ostertagia ostertagi - Adult and L₄ (including inhibited larvae)
Haemonchus placei - Adult and L₄
Trichostrongylus axei - Adult and L₄
Trichostrongylus colubriformis - Adult and L₄
Cooperia oncophora - Adult and L₄
Cooperia pectinata - Adult
Cooperia punctata - Adult and L₄
Cooperia spatulata - Adult
Cooperia sumabada - Adult and L₄
Bunostomum phlebotomum - Adult
Nematodirus helvetianus - Adult and L₄
Oesophagostomum radiatum - Adult and L₄

Lungworms

Dictyoacaulus viviparus - Adult and L₄

Cattle Grubs

Hypoderma bovis
Hypoderma lineatum

Mites

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

Lice

Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Bovicola (Damalinia) bovis

Horn Flies

Haematobia irritans

Management Considerations for External Parasites

For most effective external parasite control, CYDECTIN Pour-On should be applied to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to apply CYDECTIN Pour-On in your location to effectively control horn flies and external parasites. CYDECTIN Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product should be used as part of an integrated control program utilizing other methods to provide extended control.

Persistent Activity

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

DOSAGE

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

Body Weight Lb (kg)	Dose mL	Body Weight Lb (kg)	Dose mL
88 (40)	4	330 (150)	15
110 (50)	5	440 (200)	20
132 (60)	6	550 (250)	25
154 (70)	7	660 (300)	30
176 (80)	8	770 (350)	35
198 (90)	9	880 (400)	40
220 (100)	10	990 (450)	45
242 (110)	11	1100 (500)	50
264 (120)	12	1210 (550)	55
286 (130)	13	1320 (600)	60
308 (140)	14	1430 (650)	65

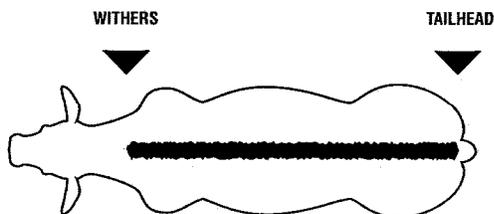


Figure 1. Where to Apply CYDECTIN Pour-On

Use Conditions

Varying weather conditions, including rainfall, do not affect the efficacy of CYDECTIN Pour-On.

ADMINISTRATION

CYDECTIN Pour-On is available in three convenient package styles designed for ease of administration and the number of cattle to be treated. Directions for use of each container type follow:

Squeeze-Measure-Pour System (16.91 fl oz/500 mL and 33.81 fl oz/1 L Bottles)

Determine the weight of the animal, calculate the recommended volume of CYDECTIN Pour-On and locate the volume marker equivalent to this dose on the dosing chamber of the bottle. Remove the dosing chamber cap and squeeze the main chamber of bottle until the desired level of solution is present in the dosing chamber. Release pressure on the container to avoid further filling. Holding the dosing chamber as shown below, pour this measured volume of solution evenly along the backline of the animal from the withers to the tailhead (see Figure 1).

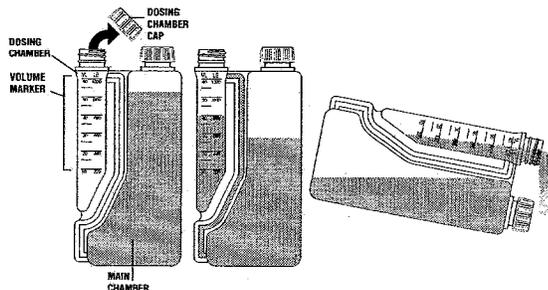


Figure 2. Squeeze-Measure-Pour System
(16.91 fl oz/500 mL and 33.81 fl oz/1 L Bottles)

Large Conventional Containers (84.54 fl oz/2.5 L and 169 fl oz/5 L Bottles and 338 fl oz/10 L Cubetainer)

These bottles are designed for use with the CYDECTIN (moxidectin) Pour-On applicators. Simply remove the transient cap and seal and replace with the vented cap. Attach the applicator feeder hose to the vented cap. Invert the container prior to use (2.5 L and 5 L containers only). Apply the recommended volume of CYDECTIN Pour-On evenly along the backline of the animal from the withers to the tailhead (see Figure 1).

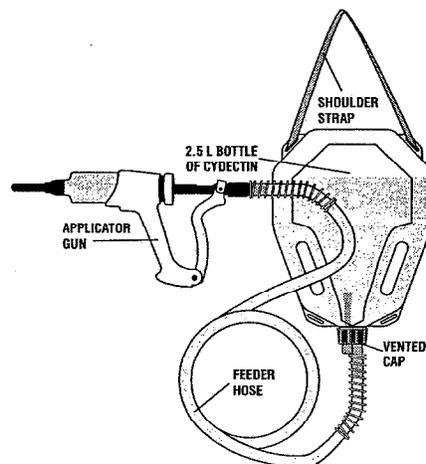


Figure 3. Large Conventional Containers
(84.54 fl oz/2.5 L and 169 fl oz/5 L Bottles)

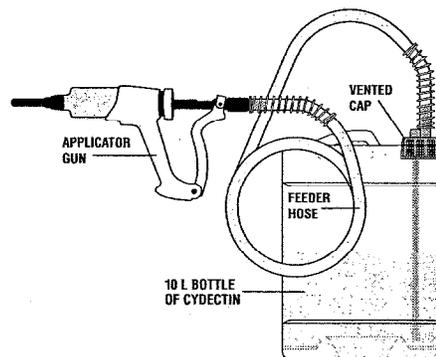


Figure 4. Large Conventional Container
(338 fl oz/10 L Cubetainer)

ANIMAL SAFETY

Tolerance and toxicity studies have demonstrated an adequate margin of safety to allow treatment of cattle of all ages with CYDECTIN Pour-On. No toxic signs were seen in cattle given up to 25 times the recommended dose level. Newborn calves similarly showed no toxic signs when treated with up to three times the recommended dose level within 12 hours of birth and nursing from cows concurrently treated with the recommended dose level of CYDECTIN Pour-On. In breeding animals (bulls and cows in estrous and during early, mid and late pregnancy), treatment with three times the recommended dose level had no effect on breeding performance.

WARNING

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

NDC 0856-2680-01

CYDECTIN[®]

moxidectin
**Pour-On for Beef
and Dairy Cattle**
Antiparasitic

Contains 5 mg
moxidectin/mL

Treats 20
550 lb cattle

Contents
500 mL

U.S. Patent No. 4,916,354
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
NADA 141-099, Approved by FDA



FORT DODGE[®]

L076P

26801

CYDECTIN®

moxidectin

INDICATIONS: CYDECTIN Pour-On is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the lay of the back from the withers to the crotch. Due to the angular tops characteristic of most dairy breeds, it is recommended that all pour-on products be applied slowly to dairy cows. Apply to healthy skin avoiding any moose, sores, open lesions, mud or mud-soaked areas. The pour-on is easily recognized by its characteristic yellow color which will maintain a short period of time after treatment. The recommended rate of administration is 4 mL for each 22 lb (10 kg) body weight which provides 1.5 mg moxidectin for each 22 lb (10 kg) body weight.

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

A copy of the minimum safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-800-333-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-3363.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk-withdrawal time are required. Meat and milk from cattle treated with CYDECTIN Pour-On may be used for human consumption at any time following treatment. A withdrawal period has not been established for the product in pre-ruminant livestock. Do not use for calves to be processed for veal.

PRECAUTIONS: For external use only.

ENVIRONMENTAL SAFETY: Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE: Store product at or below 60°F in a noncombustible container.

Acute toxicity to humans is low (LD₅₀ 1777 mg/kg body weight). It becomes frozen, thaw completely and shake well prior to use.

DISPOSAL: Dispose of containers in an approved landfill or incinerator.

See package insert for complete administration and dosage information.



Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

922985

For the Treatment of Infections and Infestations Due to Internal and External Parasites of Beef and Dairy Cattle

moxidectin

CYDECTIN®

CYDECTIN®

moxidectin

CYDECTIN (moxidectin) Pour-On when applied at the recommended dose level of 0.5 mg/22 lb (0.5 mg/kg) body weight is effective in the treatment and control of the following internal (adult and fourth-stage larvae (L4)) and external parasites:

 Gastrointestinal Nematodes:	Adult and L ₄ (including inhibited larvae)	Cattle Grease:	<i>Hypoderma bovis</i> <i>Hypoderma lineatum</i>
<i>Haemonchus placei</i>	Adult and L ₄	Mites:	<i>Otodectes cynis</i> <i>Psoroptes ovis</i> <i>Psoroptes communis var. bovis</i>
<i>Haemonchus contortus</i>	Adult and L ₄	Lice:	<i>Licophotus vituli</i> <i>Haematopinus eurysternus</i> <i>Ctenocephalides felis</i>
<i>Osthorosia circumcincta</i>	Adult and L ₄	Horn Flies:	<i>Haematobia irritans</i>
<i>Cyathostomum pygmaeum</i>	Adult and L ₄		
<i>Trichostrongylus axei</i>	Adult and L ₄		
<i>Oesophagostomum radiatum</i>	Adult and L ₄		
Leishmaniasis:	Adult and L ₄		
<i>Phlebotomus papatasi</i>	Adult and L ₄		

CYDECTIN Pour-On has been proven to effectively control infections and protect from reinfection with *Haemonchus placei* for 31 days after treatment, *Cyathostomum radiatum* and *Osthorosia circumcincta* for 28 days after treatment and *Trichostrongylus axei* for 42 days after treatment. Efficacy below 50% was observed in some *Osthorosia circumcincta* (estrus/persistent) activity studies at 21 and 28 days posttreatment.

For most effective external parasite control, CYDECTIN Pour-On should be applied to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or livestock entomologist for the most appropriate time to apply CYDECTIN Pour-On in your location to effectively control horn flies and external parasites. CYDECTIN Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product should be used as part of an integrated control program utilizing other methods to provide extended control.



FORT DODGE
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA



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CYDECTIN®

moxidectin

WARNING

Not For Use in Humans. Keep this and all drugs out of the reach of children. The product may cause irritation to skin, eyes, or mucous membranes. In case of accidental skin contact, wash thoroughly with soap and water and launder clothing. If it gets on, in case of accidental eye contact, flush eyes with copious amounts of water. When direct inhalation occurs, cleanse nose and respiratory passages with fresh air. In case of ingestion do not induce vomiting and seek medical attention immediately. If irritation or any other symptoms attributable to exposure to this product persists, consult your physician.

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-255-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1395.

RESIDUE WARNING

When used according to label directions, sufficient pre-slaughter drug withdrawal periods are required. Meat and milk from cattle treated with CYDECTIN (moxidectin) Pour-On should be used for human consumption at any time following treatment. A withdrawal period has not been established for the product in pre-arranging calves. Do not use in calves to be processed for veal.

PRECAUTIONS

For external use only. Do not apply to areas of skin with severe scars, skin lesions, mud or crusting. CYDECTIN Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.

ENVIRONMENTAL SAFETY

Studies indicate that when moxidectin comes in contact with the soil it readily and rapidly binds to the soil and becomes inactive. The moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE

Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL

Dispose of containers in an approved landfill or by incineration.

CYDECTIN®

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

**Zero Slaughter Withdrawal
Not for Use in Veal Calves.
Zero Milk Discard**

Treats 20 - 550 lb cattle



FORT DODGE
FORT DODGE ANIMAL HEALTH
U.S. Patent No. 4,916,154

CYDECTIN®

moxidectin

Dosage: CYDECTIN (moxidectin) Pour-On is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the top of the back from the withers to the tailhead. Due to the original top-line characteristics of most dairy breeds, it is recommended that all pour-on products be applied slowly to dairy cows. Apply to healthy skin avoiding any charge cuts, skin lesions, mud or manure. Treated cattle can be easily recognized by the characteristic purple color which will remain for a short period of time after treatment. The recommended rate of administration is 1 mL for each 22 lb (10 kg) body weight which provides 0.5 mg moxidectin. For each 22 lb (0.5 mg/kg) body weight. The table below will assist in the calculation of the appropriate volume of pour-on which must be applied based on the weight of animal being treated.

Dosage Table

Body Weight (lb)	Dose (mL)	Body Weight (kg)	Dose (mL)
30 (14)	1.4	3.3 (1.5)	1.5
40 (18)	1.8	4.4 (2.0)	2.0
50 (23)	2.3	5.5 (2.5)	2.5
60 (27)	2.7	6.6 (3.0)	3.0
70 (32)	3.2	7.7 (3.5)	3.5
80 (36)	3.6	8.8 (4.0)	4.0
90 (41)	4.1	9.9 (4.5)	4.5
100 (45)	4.5	11.0 (5.0)	5.0
110 (50)	5.0	12.1 (5.5)	5.5
120 (55)	5.5	13.2 (6.0)	6.0
130 (60)	6.0	14.3 (6.5)	6.5

See package insert for complete administration and dosage information. See bottom of case for lot number and expiration date.

Contents 500 mL

NADA 141-009 Approved by FDA



8538 00951 2681CD

8538 2681CD 8538 2681CD

8538 2681CD

NDC 0856-2680-02

CYDECTIN[®]

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

Treats 40-550 lb cattle

For the Treatment of Infections and
Infestations Due to Internal and External
Parasites of Beef and Dairy Cattle

Contents
1 L

U.S. Patent No. 4,916,164
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
NADA 141-099. Approved by FDA

FORT DODGE



2683D

LOT/EXP

CYDECTIN®

moxidectin

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

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

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-800-338-5761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1335.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter dairy withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN Pour-On may be used for human consumption at any time following treatment. 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: For external use in cattle only.

ENVIRONMENTAL SAFETY: Do not contaminate water by direct application or by improper disposal of this container.

STORAGE: Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL: Dispose of containers in an approved landfill or by incineration.

FORT DODGE

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

2604B
02/179



Pour-On for Beef and Dairy Cattle

moxidectin
CYDECTIN

For the Treatment of Infections and Infestations Due to Internal and External Parasites of Beef and Dairy Cattle

CYDECTIN

moxidectin

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

Gastrointestinal Roundworms

- Ostertagia ostertagi* - Adult and L4
- Haemonchus placei* - Adult and L4 (including inhibited larvae)
- Tichostrongylus axei* - Adult and L4
- Tichostrongylus colubriformis* - Adult and L4
- Cooperia oncophora* - Adult and L4
- Cooperia plicata* - Adult
- Cooperia punctata* - Adult and L4
- Cooperia spatulata* - Adult
- Cooperia sunnhada* - Adult and L4
- Diplostomum phloeoformum* - Adult
- Nematodirus helveticus* - Adult and L4
- Oesophagostomum radiatum* - Adult and L4
- Lungworms**
- Dictyocaulus viviparus* - Adult and L4

Cattle Grubs

- Hypoderma bovis*
- Hypoderma lineatum*

Mites

- Chorioptes bovis*
- Psoroptes ovis* (*Favosites communis* var. *bovis*)

Lice

- Linognathus setosus*
- Haematopinus eurysternus*
- Solenopotes capillatus*
- Bovicola* (*Damalina*) *bovis*

Horn Flies

- Haematobia irritans*

CYDECTIN Pour-On has been proven to effectively control infestations and protect from reinfection with *Haematobia irritans* placed for 14 days after treatment, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days after treatment, and *Dictyocaulus viviparus* for 42 days after treatment. Efficacy below 90% was observed in some *Ostertagia ostertagi* persistent activity studies at 21 and 28 days post-treatment.

For most effective external parasite control, CYDECTIN Pour-On should be applied to all cattle in the herd. Cattle entering the herd to avoid this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to apply CYDECTIN Pour-On to your location to effectively control horn flies and external parasites. CYDECTIN Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product should be used as part of an integrated control program utilizing other methods to provide extended control.



Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

CYDECTIN

moxidectin

WARNING

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

A copy of the most recent safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-238-6791. To report adverse reactions attributable to exposure to this product call 1-800-477-4395.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN (moxidectin) Pour-On may be used for human consumption at any time following treatment. A withdrawal period has not been established for this product in pre-ruminant calves. Do not use in calves to be processed for veal.

PRECAUTIONS

For external use only. Do not apply to areas of skin with minge scabs, skin lesions, mud or manure. CYDECTIN Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for topical use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.

ENVIRONMENTAL SAFETY

Studies indicate that when moxidectin comes in contact with the soil, it readily and highly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE

Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL

Dispose of containers in an approved landfill or by incineration.

NDC 0856-2680-02

CYDECTIN

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

Zero Slaughter Withdrawal.
Not for Use in Veal Calves.
Zero Milk Discard.

Treats 40 - 550 lb cattle

For the Treatment of Infections and Infestations Due to Internal and External Parasites of Beef and Dairy Cattle

Contents 1 L

NADA 141-090 Approved by FDA



Fort Dodge Animal Health
U.S. Patent No. 4,916,154

CYDECTIN

moxidectin

Dosage: CYDECTIN (moxidectin) Pour-On is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the top of the back from the withers to the tailhead. Due to the irregular topology and anatomy of most dairy breeds, it is recommended that all pour-on products be applied slowly to dairy cows. Apply to healthy skin avoiding any minge scabs, skin lesions, mud or manure. Treated cattle can be easily recognized by the characteristic purple color, which will remain for a short period of time after treatment. The recommended rate of administration is 1 mL/101 each 22 lb (10 kg) body weight which provides 0.5 mg moxidectin for each 2.2 lb (1.0 kg) body weight. The table below will assist in the calculation of the appropriate volume of pour-on which must be applied based on the weight of an animal being treated.

Dosage Table

Body Weight (lb)	Dose (mL)	Body Weight (kg)	Dose (mL)
80 (36)	4	330 (150)	15
100 (45)	5	340 (200)	20
120 (54)	6	350 (250)	25
150 (68)	7	660 (300)	30
175 (79)	8	770 (350)	35
190 (86)	9	380 (400)	40
220 (100)	10	990 (450)	45
240 (110)	11	1100 (500)	50
254 (120)	12	1210 (550)	55
280 (127)	13	1320 (600)	60
300 (140)	14	1430 (650)	65

See package insert for complete administration and dosage information. See bottom or side for lot number and expiration date.

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2683CD



NDC 0856-2680-03

CYDECTIN[®]

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

Treats 100 550 lb cattle

**For the Treatment of Infections
and Infestations Due to Internal
and External Parasites of
Beef and Dairy Cattle**



Contents **2.5 L**

FORT DODGE[®]

U.S. Patent No. 4,916,154
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
NADA 141-069, Approved by FDA

01630

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Lot
Exp.



CYDECTIN[®]

moxidectin

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

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

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1365.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN Pour-On may be used for human consumption at any time following treatment. 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: For external use in cattle only.

ENVIRONMENTAL SAFETY: Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE: Store product at or below room temperature. Avoid prolonged exposure above 25 C (77 F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL: Dispose of containers in an approved landfill or by incineration.

See package insert for complete administration and dosage information.

FORT DODGE[®]

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

2689B
9237



For the Treatment of Infections and Infestations Due to Internal and External Parasites of Beef and Dairy Cattle

Pour-On for Beef and Dairy Cattle

moxidectin

CYDECTIN

CYDECTIN

moxidectin

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

Gastrointestinal Roundworms

- Ostertagia ostertagi* - Adult and L₄ (including inhibited larvae)
- Haemonchus placei* - Adult and L₄
- Trichostrongylus axei* - Adult and L₄
- Trichostrongylus colubriformis* - Adult and L₄
- Cooperia oncophora* - Adult and L₄
- Cooperia pectinata* - Adult
- Cooperia punctata* - Adult and L₄
- Cooperia spatulata* - Adult
- Cooperia surrnbada* - Adult and L₄
- Bunostomum phlebotomum* - Adult
- Nematodirus helvetianus* - Adult and L₄
- Oesophagostomum radiatum* - Adult and L₄

Lungworms

- Dictyocaulus viviparus* - Adult and L₄

Cattle Grubs

- Hypoderma bovis*
- Hypoderma lineatum*

Mites

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

Lice

- Linognathus vituli*
- Haematopinus euysternus*
- Solenopotes capillatus*
- Bovicola* (*Damalinea*) *bovis*

Horn Flies

- Haematobia irritans*

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

For most effective external parasite control, CYDECTIN Pour-On should be applied to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to apply CYDECTIN Pour-On in your location to effectively control horn flies and external parasites. CYDECTIN Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product should be used as part of an integrated control program utilizing other methods to provide extended control.



FORT DODGE

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA



CYDECTIN

moxidectin

WARNING

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

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1365.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN (moxidectin) Pour-On may be used for human consumption at any time following treatment. 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

For external use only. Do not apply to areas of skin with mange scabs, skin lesions, mud or manure. CYDECTIN Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for topical use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.

ENVIRONMENTAL SAFETY

Studies indicate that when moxidectin comes in contact with the soil it readily and highly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE

Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL

Dispose of containers in an approved landfill or by incineration.

NDC 0856-2680-03

CYDECTIN

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

**Zero Slaughter Withdrawal.
Not for Use in Veal Calves.
Zero Milk Discard.**

Treats 100 550 lb cattle

For the Treatment of Infections and Infestations Due to Internal and External Parasites of Beef and Dairy Cattle

Contents: 2.5 L

NADA 141-096, Approved by FDA



FORT DODGE

FORT DODGE ANIMAL HEALTH

U.S. Patent No. 4,916,114

CYDECTIN

moxidectin

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

Dosage Table

Body Weight (lb)	Dose (mL)	Body Weight (kg)	Dose (mL)
88 (40)	4	390 (150)	15
110 (50)	5	440 (200)	20
132 (60)	6	490 (250)	25
154 (70)	7	680 (300)	30
176 (80)	8	770 (350)	35
198 (90)	9	860 (400)	40
220 (100)	10	960 (450)	45
242 (110)	11	1050 (500)	50
264 (120)	12	1210 (550)	55
286 (130)	13	1320 (600)	60
308 (140)	14	1430 (650)	65

See package insert for complete administration and dosage information. See bottom of side for lot number and expiration date.

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8540 2686CE

NDC 0856-2680-04

CYDECTIN[®]

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

Treats 200-550 lb cattle

For the Treatment of Infections and
Infestations Due to Internal and
External Parasites of Beef
and Dairy Cattle

Contents 5 L

FORT DODGE[®]

U.S. Patent No. 4,916,154
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
NADA 141,099, Approved by FDA



91449



2687D

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CYDECTIN®

moxidectin

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

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

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1365.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN Pour-On may be used for human consumption at any time following treatment. 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: For external use in cattle only.

ENVIRONMENTAL SAFETY: Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE: Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL: Dispose of containers in an approved landfill or by incineration.

See package insert for complete administration and dosage information.

FORT DODGE®

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

260888
92378

NADA 141-099, Approved by FDA

CYDECTIN[®]

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

For Treatment of Infections and Infestations Due to
Internal and External Parasites of Beef and Dairy Cattle

Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. If animals are likely to be reinfected following treatment, a strategic parasite control program should be established.

MODE OF ACTION

Moxidectin is an endectocide in the milbemycin chemical class which shares the distinctive mode of action characteristic of macrocyclic lactones. CYDECTIN (moxidectin) Pour-On is specially formulated to allow moxidectin to be absorbed through the skin and distributed internally to the areas of the body affected by endo- and/or ectoparasitism. Moxidectin binds selectively and with high affinity to glutamate-gated chloride ion channels which are critical to the function of invertebrate nerve and muscle cells. This interferes with neurotransmission resulting in paralysis and elimination of the parasite.

INDICATIONS

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

Gastrointestinal Roundworms

Ostertagia ostertagi - Adult and L₄
(including inhibited larvae)
Haemonchus placei - Adult and L₄
Trichostrongylus axei - Adult and L₄
Trichostrongylus colubriformis - Adult and L₄
Cooperia oncophora - Adult and L₄
Cooperia pectinata - Adult

Cooperia punctata - Adult and L₄
Cooperia spatulata - Adult
Cooperia sumabada - Adult and L₄
Bunostomum phlebotomum - Adult
Nematodirus helvetianus - Adult and L₄
Oesophagostomum radiatum - Adult and L₄

Lungworms

Dictyocaulus viviparus - Adult and L₄

Mites

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

Horn Flies

Haematobia irritans

Cattle Grubs

Hypoderma bovis
Hypoderma lineatum

Lice

Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Bovicola (*Damalinea*) *bovis*

Management Considerations for External Parasites

For most effective external parasite control, CYDECTIN (moxidectin) Pour-On should be applied to all cattle in the herd. Cattle entering the herd following this administration should be treated prior to introduction. Consult your veterinarian or a livestock entomologist for the most appropriate time to apply CYDECTIN Pour-On in your location to effectively control horn flies and external parasites. CYDECTIN Pour-On provides seven days of persistent activity against horn flies. For optimal control of horn flies, the product should be used as part of an integrated control program utilizing other methods to provide extended control.

Persistent Activity

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

DOSAGE

CYDECTIN Pour-On is a ready-to-use topical formulation intended for direct application to the hair and skin in a narrow strip extending along the top of the back from the withers to the tailhead (see Figure 1). Due to the angular topline characteristic of most dairy breeds, it is recommended that all pour-on products be applied

slowly
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treat
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appro

Adult and L₄
Adult
Adult and L₄
Adult
Adult and L₄
Adult and L₄

slowly to dairy cows. Apply to healthy skin avoiding any mange scabs, skin lesions, mud or manure. Treated cattle can be easily recognized by the characteristic purple color, which will remain for a short period of time after treatment. The recommended rate of administration is 1 mL for each 22 lb (10 kg) body weight which provides 0.5 mg moxidectin for each 2.2 lb (0.5 mg/kg) body weight. The table below will assist in the calculation of the appropriate volume of pour-on which must be applied based on the weight of animal being treated.

Body Weight Lb (kg)	Dose mL	Body Weight Lb (kg)	Dose mL
88 (40)	4	330 (150)	15
110 (50)	5	440 (200)	20
132 (60)	6	550 (250)	25
154 (70)	7	660 (300)	30
176 (80)	8	770 (350)	35
198 (90)	9	880 (400)	40
220 (100)	10	990 (450)	45
242 (110)	11	1100 (500)	50
264 (120)	12	1210 (550)	55
286 (130)	13	1320 (600)	60
308 (140)	14	1430 (650)	65

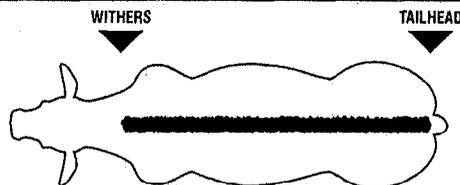


Figure 1. Where to Apply CYDECTIN Pour-On

Apply to all cattle in
your herd. Consult your
veterinarian for
CYDECTIN Pour-On in your
herd every seven days of
the year as part of an

effective control of
Haemonchus
for 28 days after
treatment in some

cases of hair and skin in
fections (see Figure 1). Due to the
nature of the product, it is applied

Use Conditions

Varying weather conditions, including rainfall, do not affect the efficacy of CYDECTIN Pour-On.

ADMINISTRATION

CYDECTIN Pour-On is available in three convenient package styles designed for ease of administration and the number of cattle to be treated. Directions for use of each container type follow:

Squeeze-Measure-Pour System (16.91 fl oz/500 mL and 33.81 fl oz/1 L Bottles)

Determine the weight of the animal, calculate the recommended volume of CYDECTIN Pour-On and locate the volume marker equivalent to this dose on the dosing chamber of the bottle. Remove the dosing chamber cap and squeeze the main chamber of bottle until the desired level of solution is present in the dosing chamber. Release pressure on the container to avoid further filling. Holding the dosing chamber as shown below, pour this measured volume of solution evenly along the backline of the animal from the withers to the tailhead (see Figure 1).

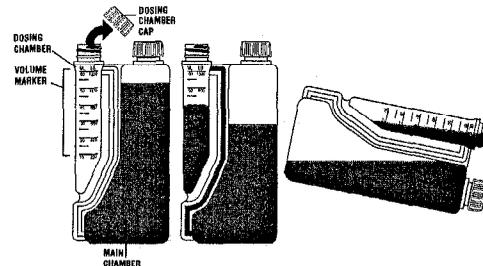


Figure 2. Squeeze-Measure-Pour System (16.91 fl oz/500 mL and 33.81 fl oz/1 L Bottles)

Large Conventional Containers (84.54 fl oz/2.5 L and 169 fl oz/5 L Bottles and 338 fl oz/10 L Cubetainer)

These bottles are designed for use with the CYDECTIN Pour-On applicators. Simply remove the transit cap and seal and replace with the vented cap. Attach the applicator feeder hose to the vented cap. Invert the container prior to use (2.5 L and 5 L containers only). Apply the recommended volume of CYDECTIN Pour-On evenly along the backline of the animal from the withers to the tailhead (see Figure 1).

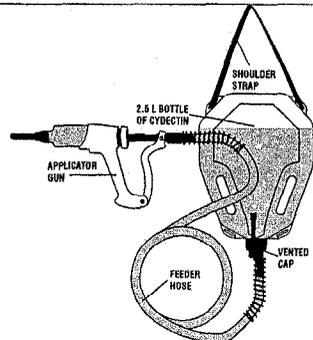


Figure 3. Large Conventional Containers (84.54 fl oz/2.5 L and 169 fl oz/5 L Bottles)

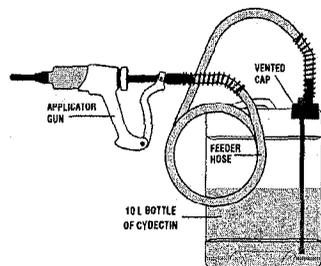


Figure 4. Large Conventional Container (338 fl oz/10 L Cubetainer)

ANIMAL SAFETY

Tolerance and toxicity studies have demonstrated an adequate margin of safety to allow treatment of cattle of all ages with CYDECTIN (moxidectin) Pour-On. No toxic signs were seen in cattle given up to 25 times the recommended dose level. Newborn calves similarly showed no toxic signs when treated with up to three times the recommended dose level within 12 hours of birth and nursing from cows concurrently treated with the recommended dose level of CYDECTIN Pour-On. In breeding animals (bulls and cows in estrous and during early, mid and late pregnancy), treatment with three times the recommended dose level had no effect on breeding performance.

WARNING

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

A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1365.

RESIDUE WARNING

When used according to label directions, neither a pre-slaughter drug withdrawal period nor a milk discard time are required. Meat and milk from cattle treated with CYDECTIN Pour-On may be used for human consumption at any time following treatment. 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

For external use only. Do not apply to areas of skin with mange scabs, skin lesions, mud or manure. CYDECTIN Pour-On is not recommended for use in species other than cattle. This product has been formulated specifically for topical use in cattle and should not be used in other animal species or by other routes of administration as adverse reactions may occur.

CYDECTIN Pour-On is effective against the migrating stage of cattle grubs (*Hypoderma* larvae). Treatment with CYDECTIN Pour-On during the period when grubs are migrating through vital areas may cause undesirable host-parasite reactions. Killing *H. lineatum* when they are located in peri-esophageal tissues may cause bloat. Killing *H. bovis* when they are in the vertebral canal may cause staggering or hindlimb paralysis. Cattle should be treated as soon as possible after heel fly (warble fly) season to avoid this potential problem. Cattle treated with CYDECTIN Pour-On at the end of fly season can be re-treated during the winter without danger of grub-related

reactions. Consult correct time to treat

Studies indicate it becomes inactive. contaminate water

Store product at 0 frozen, thaw compl

Dispose of contain

CYDECTIN (moxi 0856-2680-01) and pour polyethylene t 1/2 fl oz/5 L (NDC 0856 available for use with U.S. Patent No. 4

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reactions. Consult your veterinarian for more information regarding these secondary grub reactions and the correct time to treat with CYDECTIN Pour-On.

ENVIRONMENTAL SAFETY

Studies indicate that when moxidectin comes in contact with the soil it readily and tightly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE

Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL

Dispose of containers in an approved landfill or by incineration.

PACKAGE INFORMATION

CYDECTIN (moxidectin) Pour-On is available in five convenient container sizes. The 16.91 fl oz/500 mL (NDC 0856-2680-01) and 33.81 fl oz/1 L (NDC 0856-2680-02) are packaged in specially-designed squeeze-measure-pour polyethylene bottles. When treating larger numbers of cattle, 84.54 fl oz/2.5 L (NDC 0856-2680-03), 169 fl oz/5 L (NDC 0856-2680-04), or 338 fl oz/10 L (NDC 0856-2680-05) conventional polyethylene containers are available for use with most commercially-available topical applicators.

U.S. Patent No. 4,916,154

Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

Revised March 2001

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NDC 0856-2680-05

PEEL HERE

CYDECTIN[®]

moxidectin

Pour-On for Beef and Dairy Cattle

Antiparasitic

Contains 5 mg moxidectin/mL

Treats 400 550 lb cattle



For the Treatment of Infections and Infestations Due to
Internal and External Parasites of Beef and Dairy Cattle

Contents 10 L

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

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

RESIDUE WARNING

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A copy of the material safety data sheet (MSDS) which provides more detailed occupational safety information can be obtained by calling 1-888-339-6761. To report adverse reactions attributable to exposure to this product, call 1-800-477-1385.

PRECAUTIONS: For external use in cattle only.

ENVIRONMENTAL SAFETY: Studies indicate that when moxidectin comes in contact with the soil it readily and tightly binds to the soil and becomes inactive. Free moxidectin may adversely affect fish and certain aquatic organisms. Do not contaminate water by direct application or by improper disposal of drug containers.

STORAGE: Store product at or below room temperature. Avoid prolonged exposure above 25°C (77°F). If product becomes frozen, thaw completely and shake well prior to use.

DISPOSAL: Dispose of containers in an approved landfill or by incineration.

See package insert for complete administration and dosage information.

FORT DODGE[®]

U.S. Patent No. 4,916,154
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
NADA 141-099, Approved by FDA

2669D

NDC 0856-2680-05

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moxidectin

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