

Date of Approval: NOV 23 2005

FREEDOM OF INFORMATION SUMMARY

Supplement NADA 141-087

QUEST Gel

moxidectin

**Additional indications for the treatment and control
of *Cylicocyclus radiatus* and *Petrovinema poculatus***

Sponsored by:
Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501

2005-141-087

FOIS 3

1. General Information:

- a. File Number: NADA 141-087
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501
- Drug Labeler Code: 000856
- c. Established Name: Moxidectin
- d. Proprietary Names: QUEST Gel
- e. Dosage Form: Oral Gel
- f. How Supplied: Packaged in ready-to-use SURE-DIAL syringes. Each syringe contains adequate QUEST Gel to treat one horse with a body weight of up to 1150 lbs, or multiple horses and ponies with combined body weights of 1150 lbs.
- g. How Dispensed: OTC
- h. Amount of Active Ingredient: 20 mg moxidectin/mL (2.0% w/v)
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: The recommended dose level is 0.4 mg moxidectin/kg (2.2 lb) body weight.
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies:
- Large strongyles:**
Strongylus vulgaris – (adult and L₄/L₅ arterial stages)
Strongylus edentatus – (adult and tissue stages)
Triodontophorus brevicauda – (adults)
Triodontophorus serratus – (adults)

Small Strongyles (adults):

Cyathostomum spp., including

Cyathostomum catinatum

Cyathostomum pateratum

Cylicostephanus spp., including

Cylicostephanus calicatus

Cylicostephanus goldi

Cylicostephanus longibursatus

Cylicostephanus minutus

Cylicocyclus spp., including

Cylicocyclus insigne

Cylicocyclus leptostomum

Cylicocyclus nassatus

Cylicocyclus radiatus

Coronocyclus spp., including

Coronocyclus coronatus

Coronocyclus labiatus

Coronocyclus labratus

Gyalocephalus capitatus

Petrovinema poculatus

Small Strongyles:

Undifferentiated luminal larvae

Encysted cyathostomes:

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids:

Parascaris equorum – (adults and L₄ larval stages)

Pinworms:

Oxyuris equi - (adults and L₄ larval stages)

Hairworms:

Trichostrongylus axei - (adults)

Large-mouth stomach worms:

Habronema muscae - (adults)

Horse stomach bots:

Gasterophilus intestinalis - (2nd and 3rd instars)

Gasterophilus nasalis - (3rd instars)

One administration suppresses strongyle egg production for 84 days.

- n. Effect of Supplement: The supplement provides for the use of moxidectin gel for the treatment and control of adult *Cylicocyclus radiatus* and *Petrovinema poculatus* based on results from additional dose confirmation studies.

2. Effectiveness:

Three dose confirmation studies were conducted using a common protocol to confirm the effectiveness of QUEST Gel administered at the recommended use level of 0.4 mg moxidectin per kg body weight (2.2 lb) against endoparasites of horses. Endoparasites found at necropsy were identified to species and developmental stage.

Dose Confirmation Study 0876-E-US-20-03

Investigator: Craig R. Reinemeyer, DVM, Ph.D.

Study Location: East Tennessee Clinical Research, Rockwood, Tennessee

Animals: 24 horses (12 females, 12 males) aged 1 to 2 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 12, 13 or 14.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Dose Confirmation Study 0876-E-US-21-03

Investigator: Jenifer Edmonds, DVM, Ph.D.

Study Location: Johnson Research, Parma, Idaho

Animals: 24 horses and ponies (9 females, 6 geldings, 9 males) aged 1 to 12 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 13 or 14.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Dose Confirmation Study 0876-E-US-22-03

Investigator: Allan J. Paul, DVM, M.S.

Study Location: University of Illinois, Urbana, Illinois

Animals: 24 horses and ponies (9 females, 12 geldings, 3 males) aged 1 to 4 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 12 or 13.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Statistical Methods

Data from the 72-horse data set (36 QUEST-treated and 36 untreated controls) were subjected to appropriate statistical analyses for each parasite species in which an adequate number of untreated control animals were infected. Counts were transformed by the $Y = \log_{10}(\text{count} + 1)$ transformation prior to performing analyses. Effectiveness was calculated as:

$$\% \text{ Efficacy} = \left(\frac{\text{Mean Count Control Group} - \text{Mean Count QUEST Group}}{\text{Mean Count Control Group}} \right) * 100$$

QUEST Gel was considered effective if each of three conditions were met:

- 1) Efficacy was $\geq 90\%$ based on geometric means,
- 2) At least 6 adequately infected control horses were infected with the same specific genus/species/stage of parasite, and
- 3) The geometric mean parasite count in horses treated with QUEST Gel was significantly less than the geometric mean parasite count in untreated animals at $p < 0.05$.

Results of the three dose confirmation studies (0876-E-US-20-03, 0876-E-US-21-03 and 0876-E-US-22-03):

The cumulative data from the three dose confirmation studies demonstrate that QUEST Gel, when used at the labeled dose, is effective in the treatment and control of *Cylicoecylus radiatus* adults and *Petrovinema poculatus* adults.

3. Target Animal Safety:

This supplemental NADA does not require re-evaluation of target animal safety data. Please refer to the original NADA 141-087 Freedom of Information (FOI) summary dated July 11, 1997, and the supplemental NADA 141-087 FOI summary dated May 29, 2003.

4. Human Safety:

This drug is intended for use in horses and ponies, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician."

5. Agency Conclusions:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that QUEST Gel, when used under labeled conditions of use, is safe and effective for the treatment of the gastrointestinal parasites specified on the product label in horses and ponies six months of age and older.

QUEST Gel is available over-the-counter for lay use. Routine deworming of horses is a widely accepted and recommended practice performed by the layperson. A diagnosis of parasite infection prior to deworming is not necessary.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the indications for adult *Cylicocycclus radiatus* and *Petrovinema poculatus*, which are approved in this supplement. This exclusivity is based on the new studies conducted for substantial evidence of effectiveness.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

QUEST Gel is under the following U.S. patent:

U.S. Patent Number
4,916,154

Date of Expiration
April 10, 2007

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton

7440M

NADA 141-087, Approved by FDA

FORT DODGE[®]

QUEST[®] GEL
moxidectin

REVISED PACKAGE INSERT
ACTUAL SIZE



20

2% Equine Oral Gel
Contains 20 mg moxidectin/mL
(2.0% w/v)

DEWORMER & BOTICIDE
FOR ORAL USE IN HORSES AND PONIES
SIX MONTHS OF AGE AND OLDER

INDICATIONS

QUEST (moxidectin) 2% Equine Oral Gel when administered at the recommended dose level of 0.4 mg moxidectin/kg (2.2 lb) body weight is effective in the treatment and control of the following stages of gastrointestinal parasites in horses and ponies:

Large Strongyles:

Strongylus vulgaris – (adults and L₁/L₂ arterial stages)
Strongylus edentatus – (adults and tissue stages)
Triodontophorus brevicauda – (adults)
Triodontophorus serratus – (adults)

Small Strongyles (adults):

Cyathostomum spp., including
Cyathostomum calinatum
Cyathostomum pateratum
Cylicostephanus spp., including
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicocycclus spp., including
Cylicocycclus insigne
Cylicocycclus leptostomum
Cylicocycclus nassatus
Cylicocycclus radiatus
Coronacyclus spp., including
Coronacyclus coronatus
Coronacyclus labiatus
Coronacyclus labratus
Gyalocephalus capitatus
Petrovnhema puculatus

Small Strongyles:

Undifferentiated lumenal larvae

Encysted cyathostomes

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids

Parascaris equorum – (adults and L₄ larval stages)

Pinworms

Oxyuris equi – (adults and L₄ larval stages)

Hairworms

Trichostrongylus axei – (adults)

Large-mouth stomach worms

Habronema muscae – (adults)

Horse stomach bots

Gasterophilus intestinalis – (2nd and 3rd instars)
Gasterophilus nasalis – (3rd instars)

One administration of the recommended dose rate of QUEST (moxidectin) 2% Equine Oral Gel also suppresses strongyle egg production through 84 days.

QUEST is indicated for use in horses and ponies, including breeding mares and stallions, and foals six months of age and older.

STRATEGIC PROTECTION PROGRAMS

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. For best control of parasites, all horses and ponies should be included in a strategic treatment program, with particular attention given to high performance animals, brood mares, stallions and foals. In foals, initial treatment is recommended at 6 months of age, after which they should be included in a recurrent treatment program. Because QUEST provides effective control of the mucosal stages of small strongyles (encysted cyathostomes), it is useful in reducing the frequency of treatment required for successful strategic equine parasite control. A veterinarian can assist in preparing the best program for your needs.

QUEST 2% Equine Oral Gel when used at the recommended dose rate suppresses strongyle egg production through 84 days following a single oral administration. This residual strongyle control reduces pasture contamination and provides a period of protection from reinfection for horses and ponies maintained on the same pasture.

MODE OF ACTION

QUEST 2% Equine Oral Gel acts by interfering with chloride channel-mediated neurotransmission in the parasite. This results in paralysis and elimination of the parasite. Moxidectin is safe for use in horses and ponies because it does not have the same injurious effect on the mammalian nervous system.

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ADMINISTRATION AND DOSAGE

QUEST (moxidectin) 2% Equine Oral Gel is specially formulated as a palatable gel which is easily administered to horses and ponies. QUEST Gel is packaged in ready-to-use SURE-DIAL® syringes (see diagram of the SURE-DIAL® syringe below). The syringe is calibrated in 50-pound increments, up to 1150 pounds. This enables the administration of the recommended dose level of 0.4 mg moxidectin/kg body weight by choosing a setting consistent with the animal's weight.

HOW TO SET THE DOSE

Since the dose is based on the weight of the animal, you need to use a scale or weight tape to find each animal's weight before treating with QUEST Gel. Once the weight is known, set the dose for each horse or pony as follows.

1. Hold the syringe with the capped end pointing to the left and so that you can see the weight measurements and tick marks (small black lines) as shown in the diagram below. Each tick mark relates to 50 lbs. of body weight.
2. Turn the green dial ring until the left side of the ring lines up with the weight of the animal. In the diagram below, the dial ring is set to dose a 500 lb. animal.

HOW TO GIVE QUEST GEL TO A HORSE OR PONY

1. Make sure there is no feed in the animal's mouth.
2. Remove the cap from the end of the syringe. Save the cap for reuse.
3. Place the tip of the syringe inside the animal's mouth at the space between the teeth
4. Gently push the plunger until it stops, depositing the gel on the back of the tongue.
5. Remove the syringe from the animal's mouth and raise the animal's head slightly to make sure it swallows the gel.
6. Replace the syringe cap.

ANIMAL SAFETY

QUEST (moxidectin) 2% Equine Oral Gel can be safely administered at the recommended dose of 0.4 mg moxidectin/kg body weight to horses and ponies of all breeds at least 6 months of age or older. Transient depression, ataxia and recumbency may be seen when very young or debilitated animals are treated. In these instances, supportive care may be advisable. Reproductive safety studies demonstrate a wide margin of safety when the product is used in the treatment of estrual and pregnant mares and breeding stallions.

To report adverse drug reactions or to obtain a copy of the Material Safety Data Sheet (MSDS) call (800)477-1365.

ENVIRONMENTAL SAFETY

Care should be taken to avoid the release of significant volumes of moxidectin into either ground or free-running water since moxidectin may be injurious to aquatic life. SURE-DIAL® syringes and their contents should be disposed of in an approved landfill or by incineration.

PRECAUTIONS

QUEST 2% Equine Oral Gel has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

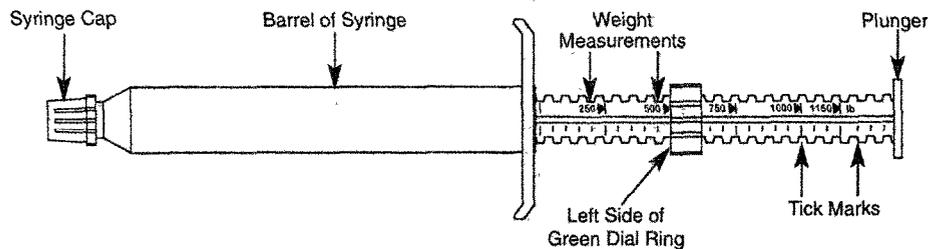
WARNINGS

Extreme caution should be used when administering the product to foals, young and miniature horses, as overdosage may result in serious adverse reactions. Do not use in sick, debilitated, or underweight animals. Not for horses or ponies intended for human consumption.

HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

SURE-DIAL® Syringe



TREATING A SECOND HORSE OR PONY WITH THE SAME SYRINGE

If the first animal you treat weighs less than 1150 lbs., there will be gel left in the syringe. You can use this gel to treat other horses or ponies. To set the next dose, add the weight of the animal you want to treat to the dose setting already on the syringe. For example, if the syringe was first used to treat a 250 lb. animal, the green dial ring is set on 250 lbs. To treat a 500 lb. animal next, move the green dial ring to the 750 lb. marking (250+500=750). You need more than one syringe to treat horses weighing more than 1150 lbs.

Each syringe of QUEST 2% Equine Oral Gel may be used to treat more than one animal especially when dosing ponies and growing and lighter breeds of horses. The table below will help estimate the number of horses or ponies the contents of each syringe will treat.

Age	Ponies		Light Horses		Heavy Horses	
	Weight (lbs)	Weight (kg)	Weight (lbs)	Weight (kg)	Weight (lbs)	Weight (kg)
6 months	200 (91)	5	400 (181)	2	550 (250)	2
9 months	250 (113)	4	500 (227)	2	700 (318)	1
Mature	450 (204)	2	900 (409)	1	1300 (590)	1

* A full syringe plus a portion of a second syringe is required to treat horses weighing more than 1150 lb.

HOW SUPPLIED

QUEST 2% Equine Oral Gel is available in one syringe applicator size. Each SURE-DIAL® syringe contains 0.4 oz (11.3 g) of QUEST 2% Equine Oral Gel which is sufficient to treat a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb.

NDC 0856-7441-03 — 0.4 oz (11.3 g) syringe - 20 mg moxidectin per mL. Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringes with the cap tightly secured.

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

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**Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA**

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QUEST^{GEL}
moxidectin

2% Equine Oral Gel
Contains 20 mg moxidectin/mL (2.0% w/w)
0.4 oz (11.3 g) moxidectin gel

HORSE DEWORMER & BOTICIDE

NDC 0956-7441-03 FOR ORAL USE IN HORSES AND PONIES SIX MONTHS OF AGE AND OLDER

ADMINISTRATION AND DOSAGE: Each syringe treats a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb. Please read entire insert for ADMINISTRATION AND DOSAGE and other important information.

WARNINGS: Extreme caution should be used when administering the product to foals, young and milking horses, as overdosage may result in serious adverse reactions. Do not use in sick, debilitated, or underweight animals. Not for horses or ponies intended for human consumption.

HUMAN WARNINGS: Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

PRECAUTION QUEST (moxidectin) Oral Gel has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

STORAGE: Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringe with the cap tightly secured.

NADA 141-087 Approved by FDA U.S. Patent No. 4,916,154

Lot
Exp. Date:

7446E 02024



Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

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**SYRINGE LABEL
ACTUAL SIZE**

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nd ponies.

Ascarids: *Parascaris equorum* - (adults and L₁ larval stages)
Pinworms: *Oxyuris equi* - (adults and L₁ larval stages)
Hairworms: *Trichostrongylus axei* - (adults)
Large-mouth stomach worms: *Habronema muscae* - (adults)

Horse stomach bots
Gasterophilus intestinalis - (2nd and 3rd instars)
Gasterophilus nasalis - (3rd instars)

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QUEST suppresses strongyle egg production through 84 days following a single oral administration. This residual strongyle control reduces pasture contamination and provides a period of protection from reinfection for horses and ponies maintained on the same pasture.

QUEST is available in the SURE-DIAL® syringe for accurate and easy dosing of your animal.

With the SURE-DIAL® syringe, you turn the dial ring to the animal's weight. You are now ready to administer the exact amount of QUEST needed for effective parasite control.

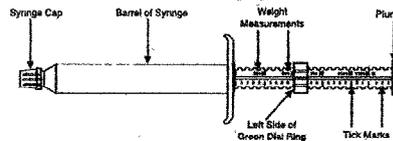
Each syringe treats a single horse weighing up to 1150 lb, or two or more lighter animals with a combined body weight of up to 1150 lb. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

larvae

QUEST is indicated for use in horses and ponies, including breeding mares and stallions, and foals six months of age and older.

Please read entire insert for ADMINISTRATION AND DOSAGE and other important information.

SURE-DIAL® Syringe



PRECAUTIONS

QUEST Oral Gel has been formulated specifically for use in horses and ponies only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

WARNINGS

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HUMAN WARNINGS

Not for use in humans. Keep this and all drugs out of the reach of children. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

STORAGE

Store at or below 77°F (25°C). Avoid freezing. If frozen, thaw completely before use. Store partially-used syringes with the cap tightly secured.

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

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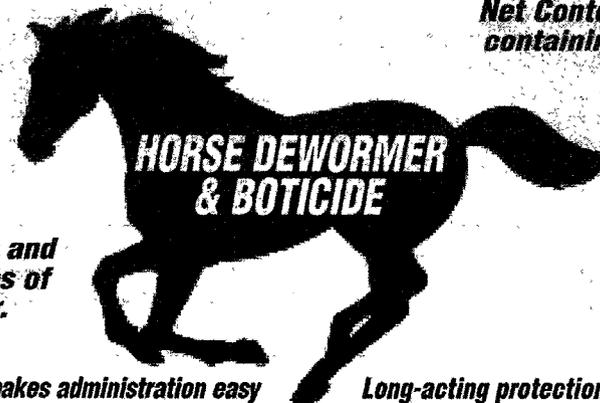
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

QUEST GEL

moxidectin
QUEST GEL



QUEST GEL
moxidectin



For use in horses and ponies six months of age and older.

Net Contents: One syringe containing 0.4 oz (11.3 g) moxidectin gel

NDC 0856-7441-03

Reduces eggs to minimize bioburden on pasture.



FORT DODGE ANIMAL HEALTH

all strongyle larvae and eggs SURE-DIAL® syringe makes administration easy

Long-acting protection for horses

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QUEST GEL
moxidectin

2% Equine Oral Gel

Contains 20 mg moxidectin/mL (2.0% w/v)

FOR ORAL USE IN HORSES AND PONIES SIX MONTHS OF AGE AND OLDER

NADA 141-067, Approved by FDA