

Date of Approval: ~~NOV 23 2~~

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA 141-216

QUEST Plus Gel

moxidectin/praziquantel

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

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

1. **General Information:**

- a. File Number: NADA 141-216
- 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 and praziquantel
- d. Proprietary Names: QUEST Plus Gel
- e. Dosage Form: Oral Gel
- f. How Supplied: Packaged in ready-to-use SURE-DIAL syringes. Each syringe contains adequate QUEST Plus Gel to treat one horse with a body weight of up to 1250 lbs, or multiple horses and ponies with combined body weights of 1250 lbs.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 20 mg moxidectin/mL (2.0% w/v) and 125 mg praziquantel/mL (12.5% w/v).
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: The recommended dose level is 0.4 mg moxidectin and 2.5 mg praziquantel/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)

Tapeworms:

Anoplocephala perfoliata - (adults)

One administration suppresses strongyle egg production for 84 days.

n. Effect of Supplement:

The supplement provides for the use of QUEST Plus gel for the treatment and control of adult *Cylicoecylus radiatus* and *Petrovinema poculatus* based on results from additional dose confirmation studies.

2. Effectiveness:

Approval of this supplemental NADA was based on three dose confirmation studies performed utilizing QUEST Gel (moxidectin). These studies support approval of QUEST Plus Gel, as QUEST Plus Gel contains the same amount of active ingredient (moxidectin 20 mg/mL) as QUEST Gel and is used at the same dose rate (0.4 mg moxidectin/kg (2.2 lb) body weight). Please refer to the supplemental NADA 141-087 Freedom of Information (FOI) Summary (2005), for a description of the three dose confirmation studies supporting this supplemental approval. Please also refer to the original NADA 141-216 FOI Summary dated May 14, 2003.

3. Target Animal Safety:

This supplemental NADA does not require re-evaluation of target animal safety data. Please refer to the original NADA 141-216 Freedom of Information (FOI) summary dated May 14, 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 Plus 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 Plus 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 *Cylicocyclus 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 Plus is under the following U.S. patent:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
4,916,154	April 10, 2007
6,893,652	July 24, 2022

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton

7520D

NADA 141-216, Approved by FDA

FORT DODGE

QUEST[®] PLUS^{GEL}

moxidectin / praziquantel



REVISED PACKAGE INSERT
ACTUAL SIZE

21

QUEST PLUS Oral Gel
Contains 20 mg moxidectin/mL (2.0% w/v)
and 125 mg praziquantel/mL (12.5% w/v)

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

INDICATIONS

QUEST PLUS (moxidectin/praziquantel) Equine Oral Gel when administered at the recommended dose level of 0.4 mg moxidectin/kg and 2.5 mg praziquantel/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 L₄/L₅ arterial stages)
Strongylus edentatus – (adults and tissue stages)
Triodontophorus brevicauda – (adults)
Triodontophorus serratus – (adults)

Small Strongyles (adults):

Cyathostomum spp., including
Cyathostomum cabnatum
Cyathostomum pateratum
Cylicostephanus spp., including
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus
Cylicocycylus spp., including
Cylicocycylus insigne
Cylicocycylus leptostomum
Cylicocycylus nassatus
Cylicocycylus radiatus
Coronocycylus spp., including
Coronocycylus coronatus
Coronocycylus labriatus
Coronocycylus labriatus
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)

Tapeworms: *Anoplocephala perfoliata* – (adults)

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

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. In foals, initial treatment is recommended at 6 months of age, after which they should be included in a recurrent treatment program. Because QUEST PLUS provides effective control of the mucosal stages of small strongyles (encysted cyathostomes) and tapeworms, 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 PLUS 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 PLUS Equine Oral Gel contains two active pharmaceutical ingredients, moxidectin and praziquantel. Moxidectin 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. Praziquantel increases the tapeworm's membrane permeability to calcium and other cations causing severe contraction and paralysis of the tapeworm's muscles. This spastic paralysis results in the inability of tapeworms to attach to the host's intestinal wall. Detached tapeworms are either destroyed by the host's immune defense system or passed in the feces.

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ADMINISTRATION AND DOSAGE

QUEST PLUS (moxidectin/praziquantel) Equine Oral Gel is specially formulated as a palatable gel which is easily administered to horses and ponies. QUEST PLUS 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 1250 pounds. This enables the administration of the recommended dose level 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 PLUS 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 blue 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 PLUS 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 PLUS (moxidectin/praziquantel) Equine Oral Gel can be safely administered at the recommended dose to horses and ponies of all breeds at least 6 months of age and older. Transient ataxia, incoordination, lethargy, depression and droopy lips and eyelids may be seen when very young or debilitated animals are treated. In these instances, supportive care may be advisable. Reproductive studies evaluating the safety of QUEST PLUS in mares at or near the time of breeding, pregnant mares and breeding stallions have not been conducted.

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 this product 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 PLUS 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.

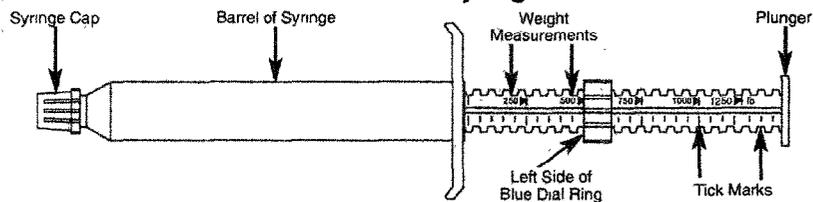
WARNINGS

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 1250 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 blue dial ring is set on 250 lbs. To treat a 500 lb. animal next, move the blue dial ring to the 750 lb. marking (250+500=750). You need more than one syringe to treat horses weighing more than 1250 lbs.

Each syringe of QUEST PLUS 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)	(kg)	Treated Animals (per syringe)	Weight (lbs)	(kg)	Treated Animals (per syringe)	Weight (lbs)	(kg)	Treated Animals (per syringe)
6 months	200	(91)	6	400	(181)	3	550	(250)	2
9 months	250	(113)	5	500	(227)	2	700	(318)	1
Mature	450	(204)	2	900	(409)	1	1300	(590)	*

* A full syringe plus a portion of a second syringe is required to treat horses weighing more than 1250 lb

HOW SUPPLIED

QUEST PLUS Equine Oral Gel is available in one syringe applicator size. Each SURE-DIAL® syringe contains 0.4 oz (11.6 g) of QUEST PLUS Equine Oral Gel which is sufficient to treat a single horse weighing up to 1250 lb, or two or more lighter animals with a combined body weight of up to 1250 lb.

NDC 0856-7521-01 — 0.4 oz (11.6 g) syringe - 20 mg moxidectin and 125 mg praziquantel 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 Nos. 4,916,154 and 6,893,652
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Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA

REVISED SYRINGE LABEL
ACTUAL SIZE

24

3.515

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Equine Oral Gel
Contains 20 mg moxidectin/mL (2.0% w/v)
and 125 mg praziquantel/mL (12.5% w/v)
0.4 oz (11.6 g) gel

QUEST PLUS[®] GEL
moxidectin/praziquantel

HORSE DEWORMER & BOTICIDE

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

NDC 006F-7521-01

ADMINISTRATION AND DOSAGE: Each syringe treats a single horse weighing up to 1250 lb, or two or more lighter animals with a combined body weight of up to 1250 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 maiden 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.

PRECAUTIONS: Quest Plus (moxidectin/praziquantel) 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 syringes with the cap tightly secured.

NADA 141-216, Approved by FDA U.S. Patent Nos. 4,816,154 and 6,893,552

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

Lot _____ Exp. Date _____

7521C 02825



42752110

2.4945

REVISED PRINTED BOX
ACTUAL SIZE

QUEST[®] PLUS (moxidectin/praziquantel) is effective in the treatment and control of the following stages of gastrointestinal parasites in horses and ponies:

Large Strongyles:

- Strongylus vulgaris* – (adults and L₄/L₅ arthenal stages)
- Strongylus edentatus* – (adults and tissue stages)
- Triodontophorus brevicauda* – (adults)
- Triodontophorus serratus* – (adults)

Small Strongyles (adults):

- Cyathostomum* spp., including
 - Cyathostomum calinaum*
 - Cyathostomum paterulum*
- Cylicostephanus* spp., including
 - Cylicostephanus calcatus*
 - Cylicostephanus goldi*
 - Cylicostephanus longibursatus*
 - Cylicostephanus minutus*
- Gyaloccephalus capitatus*
- Petrovinaema pocolatus*

Small Strongyles:

- Undifferentiated luminal larvae

Encysted cyathostomes: Late L₃ and L₄ mucosal cyathostome larvae

Ascarids: *Parascaris equorum* – (adults and L₁ 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)

Tapeworms

- Anoplocephala perfoliata* – (adults)

QUEST PLUS also 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.

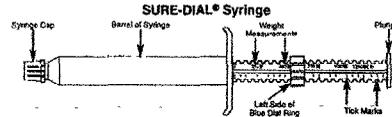
QUEST PLUS is available in the SURE-DIAL[®] syringe for accurate and easy dosing of your animal.

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 PLUS needed for effective parasite control.

Each syringe treats a single horse weighing up to 1250 lb. or two or more lighter animals with a combined body weight of up to 1250 lb. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

QUEST PLUS is indicated for use in horses and ponies six months of age and older.

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



PRECAUTIONS

QUEST PLUS 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.

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 Nos. 4,916,154 and 6,893,652

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Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA



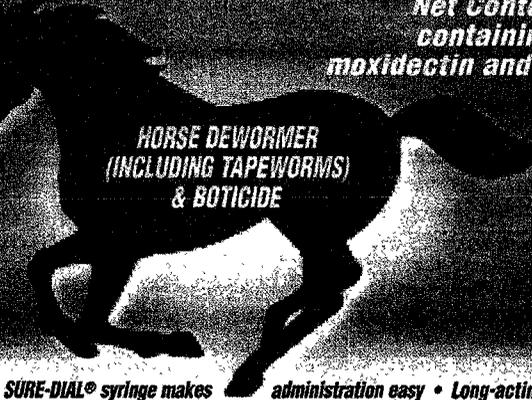
Net Contents: One syringe containing 0.4 oz (11.6 g) moxidectin and praziquantel gel

NDC 0856-7521-01

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

FORT DODGE

QUEST PLUS^{GEL}



Controls worms, bots, small strongyle larvae and eggs PLUS tapeworms • Reduces eggs to minimize bioburden on pasture • SURE-DIAL[®] syringe makes administration easy • Long-acting protection for horses

Oral Gel
dewormer (including tapeworms)
and boticide

Safety has not been evaluated in breeding and pregnant animals.

QUEST PLUS^{GEL}

Quest[®] Plus Oral Gel
Contains 20 mg moxidectin/mL (2.0% w/v)
and 125 mg praziquantel/mL (12.5% w/v)
FOR ORAL USE IN HORSES AND PONIES
SIX MONTHS OF AGE AND OLDER
NADA 141-216, Approved by FDA

9950
02525
7523D

Lot:
Exp. Date:



23

QUEST PLUS^{GEL}