

Approval Date: March 17, 2004

FREEDOM OF INFORMATION SUMMARY

NADA 141-216

QUEST PLUS Gel

moxidectin / praziquantel

Allows for the addition of new small strongyle species to the indications

Sponsored by:

Fort Dodge Animal Health

FREEDOM OF INFORMATION SUMMARY

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 Name: QUEST PLUS (moxidectin / praziquantel) Gel
- e. Dosage Form: Oral
- 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 Ingredient: Contains 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 - (adults 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

Coronocyclus spp., including

Coronocyclus coronatus

Coronocyclus labiatus

Coronocyclus labratus

Gyalocephalus capitatus

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)

Tapeworms:

Anoplocephala perfoliata – (adults)

One dose suppresses strongyle egg production for 84 days.

n. Effect of Supplement: The label descriptions of the currently-approved small strongyle genera are being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature.

2. Effectiveness:

This approval does not affect this section of the summary. Please refer to the original NADA 141-216 Freedom of information (FOI) summary dated May 14, 2003. Also, please refer to the original FOI summary for NADA 141-087 dated July 11, 1997.

3. Target Animal Safety:

This approval does not affect this section of the summary. Please refer to the original NADA 141-216 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 other 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 the 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 labeled for OTC use. Routine deworming of horses is a widely accepted and recommended practice performed by the lay person. A diagnosis of parasite infection prior to deworming is not necessary.

This approval for does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

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.

Moxidectin is under the following U.S. patent number:

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