

HFA305

OCT 25 2002

FREEDOM OF INFORMATION SUMMARY

Supplemental ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-130

Neo-Sol[®] 50 (neomycin sulfate)

For the control of mortality associated with *Escherichia coli*
organisms susceptible to neomycin sulfate in growing
turkeys.

Sponsored by:

Alpharma, Inc.

Fort Lee, NJ 07024

ANADA 200-130

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA 200-130

Sponsor: Alpharma, Inc.
One Executive Drive
Fort Lee, NJ 07024

Generic Name: neomycin sulfate

Trade Name: Neo-Sol® 50

Marketing Status: Over The Counter

Supplemental Effect: To provide for turkeys as an additional approved species based upon approval of turkeys in the pioneer product, and expiration of exclusivity period.

Pioneer: Pharmacia and Upjohn Company/Neomix® 325
NADA 011-315

II. INDICATIONS FOR USE: For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep, and goats.

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys (new).

III. DOSAGE:

A. Dosage Form: Soluble Powder

B. How Supplied: 3.5 oz (100 g) packet

C. Amount of Active Ingredient: Neomycin sulfate soluble powder contains 71.5 grams of neomycin sulfate (equivalent to 50 grams of neomycin) per packet.

D. Route of Administration Orally in drinking water (turkeys) or milk and water (other species).

E. Species: Cattle (excluding veal calves), Swine, Sheep, Turkeys (new), and Goats.

F. Labeled Dosage: Cattle, Swine, Sheep, and Goats - 10 mg/lb body weight (22 mg/kg) daily in divided doses for a maximum of 14 days.

Growing Turkeys – 10 mg/lb body weight (22 mg/kg) daily for a maximum of 5 days.

IV. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (GADPTRA) of 1988, an Abbreviated New animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which is shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, the sponsor was granted a waiver on December 1, 1993, from conducting an *in vivo* bioequivalence study for Neo-Sol® 50 and the generic product was approved on May 8, 1996. The generic product is administered as an oral solution and contains the same active ingredient and drug concentration as the pioneer and contains no inactive ingredients that may significantly affect the absorption of the active ingredient.

The basis for this supplemental ANADA approval was published in 64 FR 31498, June 11, 1999, and provided for the use of neomycin sulfate in turkey drinking water for the control of mortality claim. The exclusivity period for turkeys expired on May 9, 2002, for the pioneer product, NADA 011-315.

V. HUMAN FOOD SAFETY:

Tolerances:

The tolerances established for the pioneer product apply to the generic product. Neomycin residues in the uncooked edible tissues of cattle, swine sheep, goats and turkeys as published in 21 CFR 556.430 are:

7.2 parts per million (ppm) in kidney (target tissue) and fat, 3.6 ppm in liver, and 1.2 ppm in muscle of cattle (except veal calves), swine, sheep, and goats and a tolerance of 0.15 ppm is established in milk.

7.2 parts per million (ppm) in skin with adhering fat, 3.6 ppm in liver, and 1.2 ppm in muscle of turkeys.

Withdrawal Times (21 CFR 520.1484):

| | |
|--------------------------------|--------|
| Cattle (excluding veal calves) | 1 Day |
| Swine | 3 Days |
| Goats | 3 Days |
| Sheep | 2 Days |
| Turkeys | 0 Days |

Regulatory Method for Residues:

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Staphylococcus epidermidis* suspension. The method is published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Methods, Reports, and Protocols", revised October 1968, reprinted December 1974. The method is available from the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, Rockville Maryland 20855.

VI. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Neo-Sol® 50 when used under its proposed conditions of use, is safe and effective for its labeled indications.

Attachments:

Pioneer Labeling:

3.5 oz (100 grams) packet

Generic Labeling:

3.5 oz (100 grams) packet

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

Pioneer front label

NDC 0009-0553-40

Neomix[®] 325

Soluble Powder

neomycin sulfate (commercial grade)



LOT 60DRW
EXP 11/2004

TM

For the treatment and control of colibacillosis (Bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep and goats.

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

Each Packet Contains:

71.5 gm neomycin sulfate (commercial grade)
equivalent to 50 gm neomycin

NADA #11-315, Approved by FDA

Restricted Drug—Use Only As Directed (California)

Pharmacia
&Upjohn

NET WT 3.5 Oz (100 Grams)

Pioneer back label

For Use in Animals Only

Store at room temperature

Add to drinking water—Not for use in liquid supplements

Dosage and Administration: Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 days. Administer to cattle, swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

Herd/Flock Treatment: Each packet will treat 7150 pounds body weight. Therefore, estimate the total number of pounds of body weight of the animals to be treated and administer one (1) packet (or portion thereof) for each 7150 pounds. The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day.

Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) level teaspoon in water or milk for each 160 pounds body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

Drinking Water: Use the number of packets indicated below in 256 gallons of water, or in two gallons of stock solution used in proportioners set to meter one ounce per gallon.

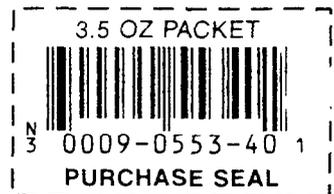
Swine:

Pigs Weighing 25 to 50 Pounds 2 Packets
Pigs Weighing 50 to 100 Pounds 3 Packets
Pigs Weighing Over 100 Pounds 4 Packets

Caution: To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression, or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep, goats, and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.



813 860 006 690445
Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

Warning: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for the appropriate species.

| | |
|---------------------------|--------|
| Turkeys | 0 days |
| Cattle | 1 day |
| Sheep | 2 days |
| Swine and goats | 3 days |

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

7 x 11 625 foil
PMS 307 (blue), PMS 551 (light blue), black

Drinking Water Swine - Use the number of packets indicated below in 256 gallons of water or in two gallons of stock solution used in proportioner set to meter one ounce per gallon.

| | |
|-----------------------------|-----------|
| Pigs weighing 25 to 50 lbs | 2 packets |
| Pigs weighing 50 to 100 lbs | 3 packets |
| Pigs weighing over 100 lbs | 4 packets |

Caution To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption. If symptoms persist after using this preparation for 2 or

3 days consult a veterinarian. If symptoms such as fever, depression or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days for cattle, swine, sheep, goats and 5 days for turkeys. Animals not drinking or eating should be treated individually by drench.

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| | |
|-----------------|--------|
| Turkeys | 0 days |
| Cattle | 1 day |
| Sheep | 2 days |
| Swine and Goats | 3 days |

A withdrawal period has not been established for this product in pre-weaning calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

Neomycin Sulfate
Antibacterial

Neo-Sol[®]
50

For the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.

For the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin sulfate in growing turkeys.

Marketed by

 **ALPHARMA**[®]

AlphaPharma Inc.
One Executive Drive, Fort Lee, New Jersey 07024

Each Packet Contains
715 gm neomycin sulfate
equivalent to 50 gm
neomycin

Store at room temperature.
Restricted drug, use only
as directed (CA)

For use in animals only

Net wt
3.5 oz (100 g)

Take Time



Observe Label
Directions

Neo-Sol is a registered trademark of AlphaPharma Inc.

ANADA #200-130, approved by FDA
AHF-009 0204

Add to drinking water -
Not for use in liquid supplements

Dosage and Administration
Administer to turkeys at a dose of 10 mg neomycin sulfate per pound of body weight per day for 5 days. Administer to cattle (excluding veal calves), swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight per day in divided doses for a maximum of 14 days.

Herd/Flock Treatment Each packet will treat 7150 pounds body weight. Therefore, estimate the total number of pounds of body weight of the animals to be treated and administer one (1) packet (or portion thereof) for each 7150 pounds. The product should be added to the amount of drinking water estimated to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required.

Fresh medicated water should be prepared each day.

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Neo-Sol