

Date of Approval: MAY 21 2004

FREEDOM OF INFORMATION SUMMARY
Original Abbreviated New Animal Drug Application

ANADA 200-372

HAN-PEN
(Penicillin G Potassium)

Soluble Powder

For the treatment of erysipelas in turkeys caused by
Erysipelothrix rhusiopathiae.

Sponsored by:
G.C. Hanford Manufacturing Co.

FREEDOM OF INFORMATION SUMMARY

1. *General Information:*

- a. File Number: ANADA 200-372
- b. Sponsor: G.C. Hanford Manufacturing Co.
P.O. Box 1017
Syracuse, NY 13201
- Drug Labeler Code: 010515
- c. Established Name: Penicillin G potassium
- d. Proprietary Name: HAN-PEN
- e. Dosage Form: Soluble powder
- f. How Supplied: 313 gram/(11 ounces) foil bags
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 0.500 billion units penicillin G potassium/foil bag
- i. Route of Administration: Oral
- j. Species/Class: Turkeys
- k. Recommended Dosage: Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.
- l. Pharmacological Category: Antibacterial
- m. Indications: For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae* in turkeys.
- n. Pioneer Product: Penicillin G Potassium, USP; NADA 55-060; Fort Dodge Animal Health

2. *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

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 has been 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 the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance, revised October 9, 2002).

Based on the formulation characteristics of the generic product, G.C.Hanford was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product HAN-PEN, Penicillin G Potassium, USP. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, Penicillin G Potassium, USP, the subject of Fort Dodge Animal Health's NADA 055-060, was approved on December 18, 1983.

3. **HUMAN SAFETY:**

• **Tolerances for Residues**

The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.01 ppm is established for penicillin and the salts of penicillin residues in the uncooked edible tissues of turkeys under 21 CFR 556.510.

• **Withdrawal Time**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time is one day.

• **Regulatory Method for Residues**

The analytical method for the detection of penicillin in tissues is a microbiological assay procedure. This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. **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 HAN-PEN (penicillin G potassium, USP), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-372:

Foil bag 313 grams (11 oz) and Pail containing 8 11-oz foil bags

Pioneer Labeling for NADA 055-060:

Foil bag-313 grams (11oz) and Pail containing 8 11-oz foil bags

Warnings

Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.
Do not use in turkeys producing eggs for human consumption.

Precautions

For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian.

LBLXXXX 01
2/2003

Manufactured by:
G.C. Hanford Manufacturing Co.
Syracuse, NY 13201 USA

FPO
Barcode

NDC10515-XXX-XX

HANFORD™
PHARMACEUTICALS

Han-Pen™

Penicillin G Potassium, USP
Antibiotic for drinking water

For oral use in turkeys only

For Veterinary use only

Store at room temperature; avoid excessive heat (104°F or 40°C).

Keep out of the reach of children.

Restricted drug (California) – Use only as directed

Active ingredient:

0.500 billion units penicillin G potassium
Nonsterile

Net Weight: 313 grams (11 ounces)

ANADA XX-XXX, Approved by FDA

Indications

For the treatment of erysipelas in turkeys (caused by *Erysipelothrix rhusopathiae*)

Dosage and administration

Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days

Directions

Combine contents and approximately 1½ pints (710 mL) of water in a glass or plastic container. Stir to dissolve. Allow concentrated solution to stand until the foam disappears. The concentrated solution should be used up or discarded within one hour after preparation.

Automatic Watering Systems – Pour the concentrated solution into a glass or plastic container then add enough water to make 2.6 gallons (9.9 liters) of stock solution. [This amount will medicate 333 gallons (1260 liters) of drinking water]. The automatic waterer should be adjusted to deliver 1 ounce (30 mL) of stock solution per gallon (3.8 liters) of drinking water. In automatic watering systems, prepare fresh solutions daily

Gravity Flow Watering Systems – Pour the concentrated solution into enough water to make 333 gallons (1260 liters) of drinking water. In gravity flow watering systems, prepare fresh solutions every 12 hours.

Drinking water prepared as directed above will contain 1,500,000 units of penicillin G per gallon (3.8 liters).

60

Section 5

Section 4

IV

V

VI

!!!

!!

NDC 10515-XXX-XX

HANFORD™
PHARMACEUTICALS

Han-Pen™

Penicillin G Potassium, USP

Antibiotic for drinking water

For oral use in turkeys only

For Veterinary use only

Store at room temperature;

avoid excessive heat (104°F or 40°C).

Keep out of the reach of children.

Restricted Drug (California) -

Use Only as Directed

**8 x 0.500 Billion Units
penicillin G potassium**

Net weight:

8 x 313 grams (11 ounces)

FPO
BarCode

ANADA XX-XXX
Approved by FDA

Manufactured by:
G.C. Hanford Mfg. Co.
Syracuse, NY 13201 USA

LBLXXXXX 01

2/2003

LOT

EXP.

241
210
2000

NDC 53501-059-02

Penicillin G Potassium USP

Antibiotic for drinking water



For oral use in turkeys only

For veterinary use only

Store at room temperature; avoid excessive heat (104°F or 40°C).

Keep out of the reach of children.

Restricted drug (under California law) – Use only as directed

Active ingredient:

0.500 billion units penicillin G potassium

Nonsterile

Net Weight: 313 grams (11 Ounces)

NADA 55-060, Approved by FDA

0000

Indications

For the treatment of erysipelas in turkeys (caused by *Erysipelothrix rhusiopathiae*).

Dosage and administration

Administer orally at a dosage of 1,500,000 units of penicillin per gallon (3.8 liters) of drinking water for 5 consecutive days.

Directions

Combine contents and approximately 1 1/2 pints (710 mL) of water in a glass or plastic container. Stir to dissolve. Allow concentrated solution to stand until the foam disappears. The concentrated solution should be used up or discarded within one hour after preparation.

Automatic Watering Systems – Pour the concentrated solution into a glass or plastic container then add enough water to make 2.6 gallons (9.9 liters) of stock solution. [This amount of solution will medicate 333 gallons (1260 liters) of drinking water]. The automatic waterer should be adjusted to deliver 1 ounce (30 mL) of stock solution per gallon (3.8 liters) of drinking water. In automatic watering systems, prepare fresh solutions daily.

Gravity Flow Watering Systems – Pour the concentrated solution into enough water to make 333 gallons (1260 liters) of drinking water. In gravity flow watering systems, prepare fresh solutions every 12 hours.

Drinking water prepared as directed above will contain 1,500,000 units of penicillin G per gallon (3.8 liters).

Warnings

Treated turkeys must not be slaughtered for food during treatment and for one day after last treatment.

Do not use in turkeys producing eggs for human consumption.

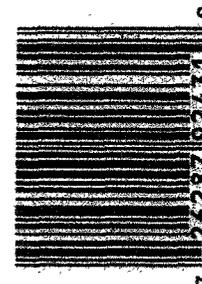
Precautions

For best results, the treatment should be started at the first sign of infection. If improvement is not noted after 3 to 4 days of treatment, consult a poultry pathologist or veterinarian.

01640
12431B

SAMPLE

Manufactured for
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
by G.C. Hanford Manufacturing Co.
Syracuse, NY 13201



00001

055-060 #30

12-17-02

*Pioneer
"copy"*

COPY



NDC 53501-059-08

Penicillin G Potassium USP

Antibiotic for drinking water



7 26287 92439 5

FORT DODGE®

For oral use in turkeys only.

For veterinary use only

Store at room temperature; avoid
excessive heat (104°F or 40°C).

Keep out of the reach of children.

Restricted drug (under California law) -

Use only as directed

**8 x 0.500 Billion Units
penicillin G potassium**

Net Weight:

8 x 313 grams (11 Ounces)

NADA 55-060, Approved by FDA

Manufactured for
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
by G.C. Hanford Manufacturing Co.
Syracuse, NY 13201

12439B

EXP APR 03