FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-256

Iron Dextran Injection - 200 (200 mg/mL)
For the prevention or treatment of iron deficiency anemia in baby pigs.

Sponsored by:

Phoenix Scientific, Inc.
3915 S 48th St. Terrace
St. Joseph, Missouri 64506-0457
FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number: 200-256

Sponsor: Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457
Drug Labeler Code: 059130

Generic Name: Iron Dextran Complex
Trade Name: Iron Dextran Injection-200

Dosage Form: Sterile Injection

How Supplied: 100 mL multiple dose vials

How Dispensed: OTC

Amount of Active Ingredients: Each mL contains 200 mg of iron as iron dextran complex

Route of Administration: IM Injection

Species: Baby pigs

Indications for Use:
Prevention: 1 mL (200 mg iron) at 1 to 3 days of age. Treatment: 1 mL (200 mg elemental iron) at the first sign of iron deficiency.


2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. Approval of an ANADA is based on a demonstration that the generic product is bioequivalent to the pioneer. Ordinarily, the ANADA sponsor shows bioequivalence and conducts a tissue residue study to establish the withdrawal time for the generic product. For certain dosage forms, the agency will grant a waiver from conducting an in vivo bioequivalence study (Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Phoenix Scientific, Inc. was granted a waiver (agency letter dated August 22, 1997) from conducting an in vivo bioequivalence study for Iron Dextran Injection-200 (200 mg/mL). The pioneer and the proposed generic have the same source of supply of bulk iron dextran complex. Hence, both contain the same active and inactive ingredients in the same dosage form and concentration.

3. HUMAN SAFETY:

Tolerance

The tolerance established for the pioneer product applies to the generic product. A tolerance has not been established for iron dextran.

Withdrawal Time

When a waiver from the requirement of an in vivo bioequivalence study is granted, the withdrawal time is that previously assigned to the pioneer product. A withdrawal time for iron dextran injection has not been established.

Regulatory Method for Residues

A regulatory analytical method for residues is not required.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate caution/warning statements.
4. **AGENCY CONCLUSION:**

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 Iron Dextran Injection-200 (200 mg/mL) when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments:

- generic product labeling
- pioneer product labeling
INDICATIONS: For prevention or treatment of baby-pig anemia due to iron deficiency.

DOSEAGE AND ADMINISTRATION:
- For intramuscular injection only:
  - Prevention: 1 mL (200 mg iron) at 3 days of age. Treatment: 1 mL (200 mg iron) at the first signs of iron deficiency.

READ PACKAGE INSERT CAREFULLY BEFORE USE.

Iron Dextran Injection-200 is a sterile solution containing ferric hydroxide in complex with a low molecular weight dextran fraction equivalent to 200 mg elemental iron per mL with 0.5% phenol as a preservative.

CAUTION: Use of this product after four (4) weeks of age may cause staining of the ham muscle.

Store at controlled room temperature 59°-86°F (15°-30°C).
IRON DEXTRAN INJECTION-200
200 mg/mL
Hematinic

DESCRIPTION: Iron Dextran Injection-200 is a sterile solution containing ferric hydroxide in complex with a low molecular weight dextran fraction equivalent to 200 mg elemental iron per mL with 0.5% phenol as a preservative.

ACTIONS: Iron Dextran injection-200 is easy and economical to use. Injection into the ham is rapid, safe, effective, quickly absorbed by the blood and goes to work immediately. With Iron Dextran Injection-200, the right dosage can be given to every animal with assurance that it will be utilized. Iron deficiency anemia occurs commonly in the suckling pig, often within the first few days following birth. As body size and blood volume increase rapidly from the first few days following birth, hemoglobin levels in the blood fall due to diminishing iron reserves which cannot be replaced adequately from iron in the sow's milk. This natural deficiency lowers the resistance of the pig and scour, pneumonia or other infections may develop and lead to death of the animal. Pigs not hampered by iron deficiency anemia are more likely to experience normal growth and to maintain their normal level of resistance to disease. Adequate iron is necessary for normal, healthy, vigorous growth.

INDICATIONS: Iron Dextran Injection-200 is intended for the prevention or treatment of anemia in baby pigs due to iron deficiency.

NOTICE: Organic iron preparation injected intramuscularly into pigs beyond 4 weeks of age may cause staining of the ham muscle.

DOSAGE AND ADMINISTRATION: For the prevention of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron (1 mL) at 1 to 3 days of age. For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron (1 mL) at the first signs of anemia.

DIRECTIONS FOR USE: Disinfect rubber stopper of vial as well as site of injection. Use small needle (20 gauge 5/8 inch) that has been sterilized (boiled in water for 20 minutes). Injection should be intramuscular into the back of the ham. Place tension on the skin over the rear of the ham and inject to a depth of 1/2" or slightly more.

Iron Dextran Injection-200 cannot be considered a substitute for sound animal husbandry. If disease is present in the litter CONSULT A VETERINARIAN.

SIDE EFFECTS: Occasionally pigs may show a reaction to injectable iron, clinically characterized by prostration with muscular weakness. In extreme cases, death may result.

HOW SUPPLIED: Iron Dextran Injection-200, 200 mg/mL, is available in 100 mL multidose vials.

Store at controlled room temperature 59°-86°F (15°-30°C).

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Manufactured by Phoenix Scientific, Inc.
St. Joseph, MO 64506
INDICATIONS: For prevention or treatment of baby-pig anemia due to iron deficiency.

DOSAGE AND ADMINISTRATION: For intramuscular injection only. Prevention: 1 mL (200 mg iron) at 1-3 days of age. Treatment: 1 mL (200 mg iron) at the first signs of iron deficiency.

READ PACKAGE INSERT CAREFULLY BEFORE USE.

IRON-GARD™ is a Trademark of Fermenta Animal Health Company.

Lot No.: Exp. Date: 105EF15.10-98

IRON-GARD™ 200 is a sterile solution containing a complex of ferric hydroxide with a low molecular weight dextran fraction equivalent to 200 mg elemental iron per mL with 0.5% phenol as a preservative.

CAUTION: Use of this product after four (4) weeks of age may cause staining of the ham muscle.

Store at controlled room temperature 59°-86° F (15°-30° C).

Marketed by: Fermenta Animal Health Co. Kansas City, MO 64153

FOR USE IN ANIMALS ONLY
Keep Out of Reach of Children
NADA 124-708, Approved by FDA

NET CONTENTS: 100 mL
FERMENTA™ ANIMAL HEALTH
IRON-GARD™ 200
Injection
200 mg/mL
Iron Dextran Complex
Hematinic
NADA 134-708, Approved by FDA

DESCRIPTION: Iron-Gard 200 is a sterile solution containing ferric hydroxide in complex with a low molecular weight dextran fraction equivalent to 200 mg elemental iron per mL with 0.5% phenol as a preservative.

ACTIONS: Injectable Iron-Gard 200 is easy and economical to use. Injection into the ham is rapid, safe, effective, quickly absorbed by the blood and goes to work immediately. With injectable Iron-Gard 200, the right dosage can be given to every animal with assurance that it will be utilized. Iron deficiency anemia occurs commonly in the suckling pig, often within the first few days following birth. As body size and blood volume increase rapidly from the first few days following birth, hemoglobin levels in the blood fall due to diminishing iron reserves which cannot be replaced adequately from iron in the sow’s milk. This natural deficiency lowers the resistance of the pig and scours, pneumonia or other infections may develop and lead to death of the animal. Pigs not hampered by iron deficiency anemia are more likely to experience normal growth and to maintain their normal level of resistance to disease. Adequate iron is necessary for normal, healthy vigorous growth.

INDICATIONS: Iron-Gard 200 is intended for the prevention or treatment of anemia in baby pigs due to iron deficiency.

NOTICE: Organic iron preparation injected intramuscularly into pigs beyond 4 weeks of age may cause staining of the ham muscle.

DOSAGE AND ADMINISTRATION: For the prevention of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron (1 mL) at 1 to 3 days of age. For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron (1 mL) at the first signs of anemia.

DIRECTIONS FOR USE: Disinfect rubber stopper of vial as well as site of injection. Use small needle (20 gauge 5/8 inch) that has been sterilized (boiled in water for 20 minutes). Injection should be intramuscular into the back of the ham. Place tension on the skin over the rear of the ham and inject to a depth of 1/2” or slightly more.

Iron-Gard 200 cannot be considered a substitute for sound animal husbandry. If disease is present in the litter CONSULT A VETERINARIAN.

SIDE EFFECTS: Occasionally, pigs may show a reaction to injectable iron, clinically characterized by prostration with muscular weakness. In extreme cases, death may result.

HOW SUPPLIED: Iron-Gard 200 Injection, 200 mg/mL is available in 100 mL multidose vials.

Store at controlled room temperature 59-86°F (15-30°C).

IRON-GARD™ is a Trademark of Fermenta Animal Health Company.

ECL-1509B 9507
Marketed by:
Fermenta Animal Health Co.
Kansas City, MO 64153