IRON HYDROGENATED DEXTRAN- iron injection Sparhawk Laboratories, Inc.

IRON HYDROGENATED DEXTRAN INJECTION

HEMATINIC

For Prevention and Treatment of Iron Deficiency Anemia in Baby Pigs

NOT FOR HUMAN USE

KEEP OUT OF REACH OF CHILDREN

Approved by FDA under NADA # 138-255

DESCRIPTION

IRON HYDROGENATED DEXTRAN INJECTION is a sterile solution containing 100 mg of elemental iron per mL, stabilized with a low molecular weight hydrogenated dextran and 0.5% phenol as a preservative.

INDICATIONS

For the prevention and treatment of anemia due to iron deficiency in baby pigs.

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. Thus, the need for a readily available outside source of iron is apparent. Without this additional iron many newborn pigs may develop anemia within the first few days of life. Anemia retards growth and lowers the body defenses against disease; scours, pneumonia, and other conditions may develop. Death from anemia or infections may occur, sometimes destroying entire litters.

DOSAGE

For intramuscular injection only.

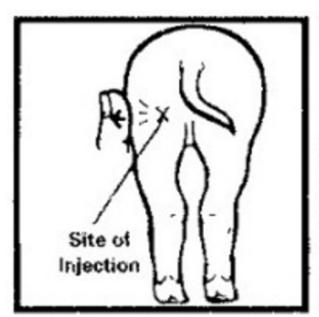
For **Prevention** of iron deficiency anemia, administer 1 mL (100 mg iron) at 2 to 4 days of age.

For **Treatment** of iron deficiency anemia, administer 1 mL (100 mg iron). Treatment may be repeated in 10 days.

DIRECTIONS FOR USE

Disinfect rubber stopper of vial and injection site with a cotton ball moistened with rubbing alcohol or other suitable disinfectant. Use a small needle (20 gauge, 5/8 inch) and syringe that have been sterilized by boiling in water for 20 minutes. Injection should be made intramuscularly into the back of the ham (see diagram below). Apply tension to the skin at the injection site by pulling skin and fat downward with pressure from the thumb or fingers. Inject into the muscle to a depth of approximately 1/2 inch. Use a

clean, sterile needle and syringe for each pig to avoid spreading infection.





PRECAUTIONS

If disease or abnormal condition is suspected, consult veterinarian before administration.

SIDE EFFECTS

Occasionally pigs may exhibit a reaction to iron injection, clinically characterized by prostration and muscular weakness. In extreme cases, death may result.

NOTICE: The intramuscular injection of organic iron preparations into pigs beyond 4 weeks of age may cause staining of muscle tissue.

HOW SUPPLIED

100 mL multiple dose vials.

Store at controlled room temperature between 15° and 30°C (59° - 86°F). Protect from freezing.

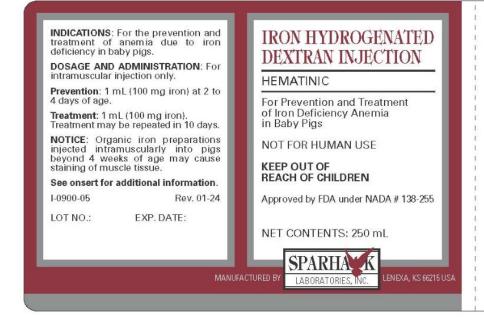
TAKE TIME OBSERVE LABEL DIRECTIONS

Use within 90 days/3months after first puncture and puncture a maximum of 70 times.

CONTACT INFORMATION

To report suspected adverse events for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Sparhawk Laboratories Inc. at

1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae



Each mL of sterile solution contains 100 mg of elemental iron stabilized with a low molecular weight hydrogenated dextran and 0.5% phenol as a preservative.

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Protect from freezing.

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5

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1

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3





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HOW SUPPLIED: 100 mL and 250 mL multiple dose vials.

Rev. 01-24

I-0900-05

2

IRON HYDROGENATED DEXTRAN

iron injection

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:58005-040

Route of Administration INTRAMUSCULAR

Active Ingredient/Active Moiety

| Ingredient Name | | | Basis of Strength | | Strength |
|--|---|-----------|--------------------------|------|-----------------------|
| IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7) | | | N | | 100 mg in 1 mL |
| | | | | | |
| | | | | | |
| Packaging | | | | | |
| # Item Code | Package Description | Marketing | Start Date | Marl | keting End Date |
| 1 NDC:58005-040-04 | 100 mL in 1 VIAL | | | | |
| | | | | | |
| | | | | | |
| Marketing Information | | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | | Marketing End Date |
| NADA | NADA138255 | | 08/11/1995 | | |
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Labeler - Sparhawk Laboratories, Inc. (147979082)

Revised: 5/2024 Sparhawk Laboratories, Inc.