

IRON 200- iron injection
Durvet, Inc.

IRON-200 (Iron Hydrogenated Dextran Injection)

Iron-200

For prevention or treatment of nursing piglet anemia due to iron deficiency.

Approved by FDA under NADA # 138-255

NOT FOR HUMAN USE

KEEP OUT OF REACH OF CHILDREN

For use in animals only

Indications: For prevention or treatment of nursing piglet 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.

Notice: Iron hydrogenated dextran injection injected intramuscularly into nursing piglets may cause muscle staining that generally resolves within 14 days after administration.

Refer to onsert and read carefully before use.

Iron-200 Injection 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.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

Use within 24 months of first puncture.

Approved by FDA under NADA # 138-255

IRON-200 INJECTION
(iron hydrogenated dextran injection)

200mg/mL

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

Actions. Injectable Iron-200 Injection 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-200 Injection, the right dosage can be given to every animal with assurance that it will be utilized. Iron deficiency anemia occurs commonly in the nursing piglet, 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 nursing piglet and scours, pneumonia or other infections may develop and lead to death of the animal. Nursing piglets 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-200 Injection is intended for the prevention or treatment of anemia in nursing piglets due to iron deficiency.

Notice: Iron hydrogenated dextran injected intramuscularly into nursing piglets may cause muscle staining that generally resolves within 14 days after administration.

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 first signs of anemia.

Warnings

Withdrawal Periods: No withdrawal period is required when used according to labeling.

User Safety Warnings: Not for use in humans. Keep out of reach of children. To obtain a Safety Data Sheet(s), contact Sparhawk Laboratories Inc at 1-800-255-6388 or at sparhawklabs.com

Animal Safety Warnings: Clinical signs associated with iron toxicity in piglets include convulsion, respiratory distress (tachypnea, dyspnea) injection site reactions (inflammation, infection or necrosis), muscle tremors or weakness, prostration, and death. There is increased risk for iron toxicity in piglets born to sows with vitamin E/ selenium deficiencies.

Directions For Use: Use a clean, sterile syringe and needle (20 gauge, ½" needle); and ensure the injection site is clean and dry. Administer intramuscularly into the back of the ham muscle to a depth of approximately ½ inch (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.



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





Side Effects: Occasionally, nursing piglets may show a reaction to injectable iron, clinically characterized by prostration with muscular weakness. In extreme cases, death may result.



Questions/Comments: Contact Sparhawk Laboratories Inc at 1-800-255-6388 or


sparhawklabs.com. To report side effects, contact Sparhawk Laboratories Inc at 1-800-255-6388. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

How Supplied: Iron-200 Injection is available in 100 mL multidose vials.

Storage, Handling, and Disposal: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).

<p>Indications: For prevention or treatment of nursing piglet anemia due to iron deficiency.</p> <p>Dosage and Administration: For Intramuscular Injection only.</p> <p>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.</p> <p>Notice: Iron hydrogenated dextran injection injected intramuscularly into nursing piglets may cause muscle staining that generally resolves within 14 days after administration. Refer to insert and read carefully before use.</p> <p>Manufactured for: DURVET, INC. Blue Springs, MO 64014 LOT NO: EXP. DATE:</p>	<p>NDC 30798-345-10</p>  <h1>Iron-200</h1> <p>(Iron Hydrogenated Dextran Injection)</p> <h2>200 MG/ML</h2> <p>For prevention or treatment of nursing piglet anemia due to iron deficiency.</p>  <p>Approved by FDA under NADA # 138-255 NOT FOR HUMAN USE KEEP OUT OF REACH OF CHILDREN For use in animals only NET CONTENTS: 100 mL (3.4 fl. oz.)</p>	<p>Iron-200 Injection 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.</p> <p>Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).</p> <p>Use within 24 months of first puncture.</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p>  <p>I-3764-04 REV 07-24 7 45801 37640 3</p> <p style="text-align: right;">OPEN HERE </p>
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<p>How Supplied: Iron-200 Injection is available in 100 mL multidose vials.</p> <p>Storage, Handling, and Disposal: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).</p> <p>Manufactured for: DURVET, INC. Blue Springs, MO 64014 7</p>	<p>Iron-200 Injection 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.</p> <p>Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F).</p> <p>Use within 24 months of first puncture</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p>  <p>I-3764-04 REV 07-24 7 45801 37640 3</p>	<p>Approved by FDA under NADA # 138-255 IRON-200 INJECTION (iron hydrogenated dextran injection) 200mg/ml.</p> <p>Description: Iron Dextrans are sterile solutions containing a complex of ferric hydroxide with a low molecular weight dextran fraction. Iron-200 Injection is equivalent to 200 mg elemental iron per mL with 0.5% phenol as a preservative.</p> <p>Actions: Injectable Iron-200 Injection 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-200 Injection, the right dosage can be given to every animal with assurance</p> <p style="text-align: center;">1</p>	<p>that it will be utilized. Iron deficiency anemia occurs commonly in the nursing piglet, 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 nursing piglet and scours, pneumonia or other infections may develop and lead to death of the animal. Nursing piglets 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.</p> <p style="text-align: center;">2</p>
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<p>Indications: Iron-200 Injection is intended for the prevention or treatment of anemia in nursing piglets due to iron deficiency.</p> <p>Notice: Iron hydrogenated dextran injected intramuscularly into nursing piglets may cause muscle staining that generally resolves within 14 days after administration.</p> <p>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 first signs of anemia.</p> <p style="text-align: center;">3</p>	<p>Warnings</p> <p>Withdrawal Periods: No withdrawal period is required when used according to labeling.</p> <p>User Safety Warnings: Not for use in humans. Keep out of reach of children. To obtain a Safety Data Sheet(s), contact Sparhawk Laboratories Inc at 1-800-255-6388 or at sparhawklabs.com</p> <p>Animal Safety Warnings: Clinical signs associated with iron toxicity in piglets include convulsion, respiratory distress (tachypnea, dyspnea), injection site reactions (inflammation, infection or necrosis), muscle tremors or weakness, prostration, and death. There is increased risk for iron toxicity in piglets born to sows with vitamin E/ selenium deficiencies.</p> <p style="text-align: center;">4</p>	<p>Directions For Use: Use a clean, sterile syringe and needle (20 gauge, ½" needle); and ensure the injection site is clean and dry. Administer intramuscularly into the back of the ham muscle to a depth of approximately ½ inch (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.</p>  <p style="text-align: center;">5</p>	<p>Iron-200 Injection cannot be considered a substitute for sound animal husbandry. If disease is present in the litter CONSULT A VETERINARIAN.</p> <p>Side Effects: Occasionally, nursing piglets may show a reaction to injectable iron, clinically characterized by prostration with muscular weakness. In extreme cases, death may result.</p> <p>Questions/Comments: Contact Sparhawk Laboratories Inc at 1-800-255-6388 or sparhawklabs.com. To report side effects, contact Sparhawk Laboratories Inc at 1-800-255-6388. For additional information about reporting side effects for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae</p> <p style="text-align: center;">6</p>
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iron injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:30798-345
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	200 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PHENOL (UNII: 339NCG44TV)	.5 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30798-345-10	100 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA138255	08/11/1995	

Labeler - Durvet, Inc. (056387798)

Registrant - Sparhawk Laboratories, Inc. (147979082)

Establishment

Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Chemdex Inc.		360684898	api manufacture

Revised: 12/2024

Durvet, Inc.