

UNIFERON 200 - iron dextran injection
Pharmacosmos, Inc

Uniferon 200

Uniferon® 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.

Keep out of the reach of children.
For use in animals only.

Uniferon® is a Trademark of Pharmacosmos A/S.

Manufactured for:
Pharmacosmos, Inc.
776 Mountain Boulevard
Watchung, NJ 07069

Issued 02-2011

NADA 134-708, Approved by FDA

Iron Dextran Complex Injection, 200 mg/mL
Iron Hydrogenated Dextran

Description: Uniferon® 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 Uniferon® 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 Uniferon® 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: Uniferon® 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.

Uniferon® 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: Uniferon® 200 Injection, 200 mg/mL is available in 100 mL multidose vials.

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

7	Uniferon® 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. Keep out of the reach of children. For use in animals only. Uniferon® is a Trademark of Pharmacosmos A/S. Manufactured for: Pharmacosmos, Inc. 776 Mountain Boulevard Watchung, NJ 07069 Issued 02-2011  3 42552 07810 7	NADA 134-708. Approved by FDA uniferon® 200 Iron Dextran Complex Injection, 200 mg/mL Iron Hydrogenated Dextran Description: Uniferon® 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. 1	Actions. Injectable Uniferon® 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 Uniferon® 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 2
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: Uniferon® 200 is intended for the prevention or treatment of anemia in baby pigs due to iron deficiency. 3	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. 4	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.  5	Uniferon® 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: Uniferon® 200 Injection, 200 mg/mL is available in 100 mL multidose vials. Store at controlled room temperature 59°-86°F (15°-30°C). 6

Lot No.: **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.
Caution: Use of this product after four (4) weeks of age may cause staining of the ham muscle.
Exp. Date: Refer to folded label attached to this container and read carefully before use.
Store at controlled room temperature 59°-86°F (15°-30°C).



NDC # 42552-078-10

uniferon® 200
Iron Dextran Complex Injection, 200 mg/mL
Iron Hydrogenated Dextran

NADA 134-708, Approved by FDA
Net Contents: 100 mL

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Watchung, NJ 07069

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Product Label

UNIFERON 200

iron dextran injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:42552-078
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iron Dextran (UNII: 95HR524N2M) (Ferric Cation - UNII:9 1O4LML6 11)	Ferric Cation	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:42552-078-10	100 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA134708	03/24/2011	

Labeler - Pharmacosmos, Inc (878028943)

Registrant - Med-Pharmex, Inc (025353699)**Establishment**

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc		025353699	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Pharmacosmos A/S		309706968	api manufacture

Revised: 9/2012

Pharmacosmos, Inc