

UNIFERON 100- iron dextran injection

Pharmacosmos, Inc

Reference Label Set Id: 69e7c883-2078-49c1-b8ea-c1d0ca7269bb

Uniferon 100

Uniferon[®] 100 is a sterile solution containing a complex of ferric hydroxide with a low molecular weight dextran fraction equivalent to 100 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

Iron Dextran Complex Injection, 100 mg/mL

Iron Hydrogenated Dextran

NADA 106-772, Approved by FDA

Description: Uniferon[®] 100 is a sterile solution containing ferric hydroxide in complex with a low molecular weight dextran fraction equivalent to 100 mg elemental iron per mL with 0.5% phenol as a preservative.

Injectable Uniferon[®] 100 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[®] 100, the right dosage can be given to every animal with assurance that it will be utilized.

Treatment of baby pigs with Uniferon[®] 100 prevents anemia and reduces losses due to iron deficiency. Adequate iron is necessary for normal, healthy, vigorous growth.

Indications: Uniferon[®] 100 is intended for the prevention or treatment of iron deficiency anemia 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. 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.

Dosage:

Intramuscular Injection

Prevention:

1 mL (100 mg iron) at 2-4 days of age.

Treatment:

1 mL (100 mg iron). May be repeated in approximately 10 days.

Directions For Use:

100mL: Use product within 60 days of first puncture. Do not Puncture the stopper more than 20 times.

250mL: Use product within 60 days of first puncture. Do not puncture the stopper more than 50 times with a needle, or more than 10 times with the trocar of an automatic self-filling injector syringe.

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.

Uniferon[®] 100 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[®] 100 Injection, 100 mg/mL is available in 100 mL and 250 mL multidose vials.

Notice: Organic iron preparation injected intramuscularly into pigs beyond 4 weeks of age may cause staining of muscle tissue.

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

Not a USP formulation.

TAKE TIME OBSERVE LABEL DIRECTIONS

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Issued 08-2016



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Iron Dextran Complex Injection, 100 mg/mL
Iron Hydrogenated Dextran

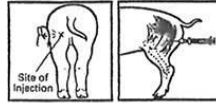
For Animal Use Only
For Intramuscular Use Only

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

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

Printed in U.S.A. Mfd. in U.S.A.

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Treatment of baby pigs with Uniferon® 100 prevents anemia and reduces losses due to iron deficiency. Adequate iron is necessary for normal, healthy, vigorous growth.

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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 (100 mg iron) at 2-4 days of age.

Treatment: 1 mL (100 mg iron). May be repeated in approximately 10 days.

Exp. Date:

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

Refer to folded label attached to this container and read carefully before use.

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

Not a USP formulation.

NDC # 42552-077-25

uniferon® 100

Iron Dextran Complex Injection, 100 mg/mL
Iron Hydrogenated Dextran

NADA 106-772, Approved by FDA

Net Contents: 250 mL



Uniferon® 100 is a sterile solution containing ferric hydroxide in complex with a low molecular weight dextran fraction equivalent to 100 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

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OPEN HERE



Lot No.:

Indications: For prevention or treatment of baby-pig anemia due to iron deficiency.

Dosage and Administration:
Intramuscular Injection.

Prevention: 1 mL (100 mg iron) at 2-4 days of age. **Treatment:** 1 mL (100 mg iron). May be repeated in approximately 10 days.

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

Read package insert before using.
For Intramuscular Use Only.

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

Not a USP formulation.

NDC # 42552-077-10

uniferon® 100

Iron Dextran Complex Injection, 100 mg/mL
Iron Hydrogenated Dextran

For Animal Use Only
KEEP OUT OF REACH OF CHILDREN

NADA 106-772, Approved by FDA
Net Contents: 100 mL



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Rev. 04-2015



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UNIFERON 100

iron dextran injection

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:42552-077
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iron Dextran (UNII: 95HR524N2M) (Ferric Cation - UNII:91O4LML611)	Ferric Cation	100 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:42552-077-25	250 mL in 1 VIAL		
2	NDC:42552-077-10	100 mL in 1 VIAL		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA106772	05/01/2017		

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: 9/2018

Pharmacosmos, Inc