

Uniferon® Customer Information Sheet

Pharmacosmos A/S Uniferon® Solution for Injection 200 mg/mL

Due to a potential animal drug shortage, the U.S. Food and Drug Administration (FDA) is temporarily permitting marketing of **Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL** in the U.S. for prevention or treatment of anemia in baby pigs due to iron deficiency.

Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL is authorized for marketing in the European Union (EU) and is similar to the **FDA-approved Pharmacosmos, Inc. Uniferon® 200, Iron Dextran Complex Injection, 200 mg/mL (NADA #134-708) product**.

The source of the non-sterile bulk solution of Iron Hydrogenated Dextran, 200 mg/mL active pharmaceutical ingredient (API) used in the production of the **Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL product** is the same source of API used in the manufacture of the **FDA-approved Pharmacosmos, Inc. Uniferon® 200, Iron Dextran Complex Injection, 200 mg/mL (NADA #134-708) product**.

Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL is manufactured in an EU inspected and authorized sterile-fill production facility in Europe, whereby it has been authorized for sale and distribution in 24 EU countries. It is not approved by the FDA.

The package insert for the **FDA-approved Pharmacosmos, Inc. Uniferon® 200, Iron Dextran Complex Injection, 200 mg/mL (NADA #134-708) product** is included herein for U.S. user reference. The vial labeling for **Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL** does not include certain headings and information present on the labeling of the FDA-approved product. U.S. users should reference the **FDA-approved Pharmacosmos, Inc. Uniferon® 200, Iron Dextran Complex Injection, 200 mg/mL** package insert in order to access the headings and information presented below:

- **Indications:** For prevention or treatment of anemia in baby pigs due to iron deficiency.
- **Dosage and Administration:** For intramuscular injection only.
 - **Prevention:** 1 mL (200 mg Iron) at 1 to 3 days of age.
 - **Treatment:** 1 mL (200 mg Iron) at the first signs of iron deficiency.
- **Caution / Notice:** Use of this product after four (4) weeks of age may cause staining of the ham muscle.

In addition, the **Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL vial label** indicates the product is authorized by EU for intramuscular (IM) and subcutaneous (SC) routes of administration; however, **the IM route of administration is the only FDA-approved route of administration**.

To report potential mis-shipments, product/manufacturing defects, product complaints, or adverse drug experiences contact Pharmacosmos, Inc., which is a fully owned U.S. subsidiary of Pharmacosmos A/S, using the contact information delineated below:

Pharmacosmos, Inc.
776 Mountain Boulevard
Watchung, NJ 07069 USA
E-mail: Uniferon.US@pharmacosmos.com
Toll Free Telephone Number: 1 (844) 744-4766

Inform the representative that your call concerns the **Pharmacosmos A/S Uniferon® Solution for Injection, 200 mg/mL x 100-mL product**, and provide product NDC and/or batch numbers, if known. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

Revision Date: 11/11/2020

NADA 134-708, Approved by FDA

Package Insert

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.

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 decrease 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 baby pigs, and scours, pneumonia or other infections may develop and lead to death of the animals. Baby 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 preparations injected intramuscularly into baby pigs beyond 4 weeks of age may cause staining of the ham muscle.

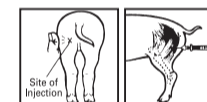
Dosage and Administration: For the prevention of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental iron (1 mL) at 1 to 3 days of age. For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 milligrams of elemental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

Directions For Use:

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

250 mL: 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. Place tension on the skin over the rear of the ham and inject to a depth of ½" or slightly more.



Uniferon® 200 cannot be considered as a substitute for sound animal husbandry. If disease is present in the litter, CONSULT A VETERINARIAN.

Side Effects: Occasionally, baby 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**, Iron Dextran Complex Injection, 200 mg/mL is available in 100 mL and 250 mL multidose vials.

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

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

Revision Date: 11/11/2020