

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml Solution for Injection for Pigs (piglet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml contains 200 mg elemental iron (Fe) as iron (III) hydroxide dextran complex.

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium chloride	
Phenol	5 mg
Water for injection	
Hydrochloric acid/sodium hydroxide (for pH adjustment)	

Slightly viscous dark brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Pig (piglet).

3.2 Indications for use for each target species

For the prevention and treatment of iron deficiency anaemia in piglets.

3.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in older pigs as ham staining may occur in animals over 4 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is advisable to stretch the skin at the injection site to minimise leakage after withdrawal of the needle. Observe aseptic precautions. Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death ^{1,2} , Hypersensitivity reaction, Injection site skin discolouration ³
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¹Associated with genetic factors or deficiency of vitamin E and/or selenium.

²Occasional piglet deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

³Transient discoloration and calcifications at the injection site.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular route.

Prevention: A single injection of 1 ml (200 mg iron) at 1-4 days of age.

Treatment: A single injection of 1 ml (200 mg iron).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

- Transferrin-iron saturation levels leading to increased susceptibility for (systemic) bacterial disease, pain, inflammation reactions as well as abscess formation at the injection site may occur
- Persistent discoloration of muscle tissue at the injection site may occur

- Iatrogenic poisoning with the following symptoms: pale mucous membranes, hemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, edema of the limbs, lameness, shock, death, liver damage. Supportive measures such as chelating agents can be used

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QB03AC

4.2 Pharmacodynamics

Iron dextran is primarily a haematinic and is effective in significantly increasing the haemoglobin levels in piglets under intensive conditions in which an all milk diet for several weeks does not provide a source of iron.

4.3 Pharmacokinetics

The iron is administered as a complex to avoid toxic effects of free iron. The iron is then stored in body tissues until required for haematopoiesis.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.

Protect from light.

Do not open the foil until ready to use the product.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material at the latest 28 days after first opening the immediate packaging.

5.4 Nature and composition of immediate packaging

Pack sizes of 5 x 100 ml, 10 x 100 ml or 12 x 200 ml multidose collapsible polyethylene vials. Vials are closed by rubber stoppers and aluminium caps. They are packed in aluminium or transparent foil.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Pharmacosmos A/S

7. MARKETING AUTHORISATION NUMBER

Vm 21674/4000

8. DATE OF FIRST AUTHORISATION

21 June 1995

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved 30 March 2026

