

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml Solution for Injection pigs (piglets)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

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

Pigs (piglets).

### 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 cases of hypersensitivity to the active substance or to any of the excipients.  
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**

Piglets:

|                                                                                   |                                                                                                      |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
| Very rare<br>(<1 animal / 10,000 animals treated,<br>including isolated reports): | Death <sup>1,2</sup><br>Hypersensitivity reaction<br>Injection site skin discolouration <sup>3</sup> |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|

<sup>1</sup>Associated with maternal dietary deficiency of vitamin E and/or selenium.

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

<sup>3</sup>Transient 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 route and dosage**

Intramuscular use.

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.

### **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**

VPA 10794/001/001

**8. DATE OF FIRST AUTHORISATION**

03/03/2006

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

22/05/2026

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).