

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Uniferon 20%, Solution for Injection.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains 200mg elemental iron (Fe) as iron dextran and 0.5%w/v phenol as a bacteriostat.

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection  
Slightly viscous dark brown solution

### **4. CLINICAL PARTICULARS**

#### **4.1 Target Species**

Piglets

#### **4.2 Indications for use, specifying the target species**

For the prevention and treatment of iron deficiency anaemia in piglets

#### **4.3 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.

#### **4.4 Special warnings for each target species**

None

#### **4.5 Special precautions for use**

i. Special precautions for use in animals

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.

- ii. Special precautions to be taken by the person administering the medicinal to the animals.

Care should be taken to avoid accidental self-injection. In the event of accidental self-injection seek urgent medical attention.

#### **4.6 Adverse reactions**

Occasional deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium. In addition, occasional piglet deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system by the iron dextran colloidal solution as it is being absorbed.

#### **4.7 Use during pregnancy, lactation or lay**

Not applicable.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.9 Amounts to be administered and administration route**

Prevention: A single dose of 1 ml (200mg iron) by deep intramuscular injection into the hind limb at 3-4 days of age.

Treatment: 1ml by deep intramuscular injection.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary**

Not applicable.

#### **4.11 Withdrawal periods**

Withdrawal period for meat: 28 days.

### **5. PHARMACOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Antianemic preparations, iron preparations, iron, parenteral preparations

**ATC Vet Code:** QB03AC

## **5.1 Pharmacodynamic properties**

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.

## **5.2 Pharmacokinetic particulars**

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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium chloride  
Phenol  
Water for injection  
Hydrochloric acid/sodium hydroxide (for pH adjustment)

### **6.2 Incompatibilities**

None known

### **6.3 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.

### **6.4 Special precautions for storage**

Do not store above 25°C  
Protect from light  
Do not open the foil sachet 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.

### **6.5 Nature and composition of immediate packaging**

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

The packaging may contain an injector

Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Pharmacosmos A/S  
Roervangsvej 30  
DK-4300 Holbaek  
Denmark

**8. MARKETING AUTHORISATION NUMBER**

**Vm** 21674/4000

**9. DATE OF THE FIRST AUTHORISATION**

**Date:** 21 June 1995

**10. DATE OF REVISION OF THE TEXT**

**Date:** March 2015

APPROVED *T. NASH* 31/03/15