

## SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Uniferon 20%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PHARMACOLOGICAL PROPERTIES

Iron dextran is primarily a haematinic and it is effective in significantly increasing haemoglobin levels of piglets kept under intensive conditions in which an all milk diet for several weeks does not provide a source of essential iron.  
ATC Vet Code: QBA30C90.

5. CLINICAL PARTICULARS

5.1 Target Species

Piglets

5.2 Indications for Use

For the prevention and treatment of iron deficiency anaemia in piglets

5.3 Contra-indications

Not applicable

5.4 Undesirable effects, frequency and seriousness

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.

5.5 Special Precautions for Use

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

5.6 Use during pregnancy and lactation

Not applicable.

5.7 Interaction with other medicaments and other forms of administration

None known.

5.8 Posology and Method of Administration

Prevention: A single dose of 1ml (200mg iron) by deep intramuscular injection into the hind limb at 2-4 days of age.

Treatment: 1ml by deep intramuscular injection in pigs up to 8 weeks of age.

Avoid the introduction of contamination during use.

5.9 Overdosage

Not applicable provided the recommended dosage is not exceeded.

5.10 Special warnings for each target species

None

5.11 Withdrawal periods

Withdrawal period for meat: zero days.

5.12 Special precautions to be taken by the Person Administering the Product to Animals

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

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities (Major)

None known.

6.2 Shelf-life

3 years.

6.3 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.

6.4 Nature and Contents of Container

Boxes of 5 x 100ml multidose collapsible polyethylene vials

6.5 Special Precautions for the disposal of unused product or waste materials if any

None.

7. FINAL INFORMATION

Name and address of Marketing Authorisation Holder

Pharmacosmos A/S  
Roervangsvej 30  
DK-4300 Holbæk  
Denmark

Name and address of Manufacturer

Pharmacosmos A/S  
Roervangsvej 30  
DK-4300 Holbæk  
Denmark

Product Licence No:  
Date of Approval of SPC:  
Date of last renewal:

Vm 21674/4000  
3 May 2006  
21 June 2005

**LEGAL CATEGORY**

**POM-VPS**