Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 20 % w/v Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Special precautions for use in animals

It is advisable to stretch the skin over the injection site, to prevent 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 the event of accidental self-injection seek urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Occasional deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with a 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 1ml (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 Period(s)

Withdrawal period for meat: 28 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code; QB03AC
Pharmacotherapeutic group: Antianemic preparations, iron preparations, iron, parenteral preparations.

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 properties

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

Phenol
Sodium chloride
Water for Injections
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^{o}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 least 28 days after first opening the immediate packaging.

6.5 Nature and composition of immediate packaging

Boxes of 5 x 100 ml or 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 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 products or waste materials

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(S)

VPA 10794/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 1994

Date of last renewal: 30th March 2009

10 DATE OF REVISION OF THE TEXT

March 2015