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 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 (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. 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 (200 mg iron) by deep intramuscular injection into the hind limb at 3-4 days of age.

Treatment: 1 ml 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 aluminium or transparent 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.

6.5 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.

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

VPA 10794/001/001

9. DATE OF THE FIRST AUTHORISATION

31st March 1994

10. DATE OF REVISION OF THE TEXT

18 July 2024