

[Version 8, 10/2012]

ANNEX I

SUMMARY OF PROPOSED PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each ml contains 200 mg iron(III) as iron(III) hydroxide dextran complex

Excipients:

Each ml contains 5 mg phenol as a preservative

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Dark brown, non transparent solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (piglets)

4.2 Indications for use, specifying the target species

In piglets: Treatment and prevention of iron deficiency anaemia

4.3 Contraindications

Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium.

Do not use in case of hypersensitivity to the active substance.

Do not use iron dextran in older pigs as meat staining may occur in animals over 4 weeks of age.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

Normal aseptic injection techniques should be practiced

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self-injection, especially people with known hypersensitivity to iron dextran. In the event of accidental self-injection seek immediate medical advice and show the package leaflet or the label to the physician. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Very rarely deaths have occurred in piglets following the administration of parenteral iron dextran preparations ("very rare" is equivalent to less than 1 animal reacting in 10,000 treated animals). These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.

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

Hypersensitivity reactions can occur.

Injections of this veterinary medicinal product may cause transient discoloration and calcifications at the injection site.

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

It may reduce the absorption of concomitantly administered oral iron

4.9 Amounts to be administered and administration route

Intramuscular or subcutaneous route.

200 mg of iron as iron dextran per piglet corresponding to 1 ml per piglet

Prevention: a single injection at 1-4 days of age

Treatment: a single injection

Due to limited studies on the bioavailability of iron dextran for the subcutaneous route of administration the intramuscular route is recommended.

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

- 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

4.11 Withdrawal period(s)

Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group

Iron, parenteral preparations

ATCvet code: QB03AC

5.1 Pharmacodynamic properties

Iron is an essential component of haemoglobin in the erythrocytes transporting oxygen to all parts of the body. The veterinary medicinal product contains iron as a stable iron(III)-hydroxide dextran complex, which is analogous to the physiological form of iron, ferritin (ferric hydroxide phosphate

protein complex). The iron is available in a non-ionic water-soluble form that has a very low toxicity compared to free iron. Iron (as iron dextran) is antianaemic by increasing the reserve in iron that is necessary for the formation of haemoglobin and the refill of enzymes linked to iron and involved in growth and resistance to infections. After administration, the ferri hydroxide dextran complex is deposited in the reticuloendothelial system, and then iron is progressively released from the complex.

5.2 Pharmacokinetic particulars

After intramuscular injection, iron dextran is absorbed rapidly from the injection site into the capillaries and the lymphatic system. Circulating iron is removed from the plasma by cells of the reticuloendothelial system which split the complex into its components of iron and dextran. The iron is immediately bound to the available protein moieties to form haemosiderin or ferritin, the physiological forms of iron, or to a lesser extent, to transferrin. The plasma half life is 5 hours for circulating iron. Small quantities of iron are eliminated in urine and faeces.

Dextran is either metabolised or excreted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride

Phenol

Water for injections

Hydrochloric acid/sodium hydroxide (for pH adjustment)

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of collapsible plastic vial as packaged for sale: 3 years

Shelf life of glass vial as packaged for sale: 3 years

Shelf-life of hard plastic vial as packaged for sale: 2 years

Shelf-life after first opening of the immediate packaging: 28 days when stored below 25°C

6.4. Special precautions for storage

Protect from frost

6.5 Nature and composition of immediate packaging

100 ml hard plastic vial (HDPE), 100 ml glass vial and 100 ml or 200 ml collapsible vial (LDPE) in aluminium sachet. Do not open the foil sachet until ready to use the veterinary medicinal product.

Carton box with 5, 12, 20 vials of 100 ml or 12 vials of 200 ml

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 materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally

10. DATE OF REVISION OF THE TEXT

12-2015

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally