[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) in 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 25ºC

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

02-2015

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally

[Version 8, 10/2012]

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

Outer carton for HDPE, LDPE and glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml solution for injection
Iron(III) as iron(III) hydroxide dextran complex

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg iron(III) as iron(III) hydroxide dextran complex and phenol as a preservative

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 x 100 ml
12 x 100 ml
20 x 100 ml
12 x 200 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m., s.c.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life once opened: 28 days below 25ºC

11. SPECIAL STORAGE CONDITIONS

Protect from frost

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE OUTER/IMMEDIATE PACKAGING

Aluminium foil sachet for LDPE vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml solution for injection
Iron(III) as iron(III) hydroxide dextran complex

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg iron(III) as iron(III) hydroxide dextran complex and phenol as a preservative

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
200 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m., s.c.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Do not remove the aluminium foil before opening and use.

10. EXPIRY DATE

EXP {month/year}
Shelf life once opened: 28 days below 25ºC
Once opened, use by __ / __ / __ /

11. SPECIAL STORAGE CONDITIONS

Protect from frost

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

HDPE, LDPE and glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml solution for injection
Iron(III) as iron(III) hydroxide dextran complex

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg iron(III) as iron(III) hydroxide dextran complex and phenol as a preservative

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
200 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

i.m., s.c.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf life once opened: 28 days below 25ºC
Once opened, use by __ / __ / __ /

11. SPECIAL STORAGE CONDITIONS

Protect from frost

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

Batch

[Version 8, 10/2012]

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Uniferon 200 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Pharmacosmos A/S
Roervangsvej 30
DK-4300 Holbaek

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Uniferon 200 mg/ml solution for injection
Iron(III) as iron(III) hydroxide dextran complex

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Uniferon 200 mg/ml is a dark brown, non transparent solution.
Each ml contains 200 mg iron(III) as iron(III) hydroxide dextran complex

4. INDICATION(S)

In piglets: Treatment and prevention of iron deficiency anaemia

5. 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

6. ADVERSE REACTIONS

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.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs (piglets)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Normal aseptic injection techniques should be practiced

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

Protect from frost

Do not use the veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of the month.

Shelf-life after first opening of the immediate packaging: 28 days below 25ºC.

12. SPECIAL WARNING(S)

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.

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

Parenteral iron may reduce the absorption of concomitantly administered oral iron.

Overdose (symptoms, emergency procedures, antidotes)
Overdosing with parenteral iron preparations may lead to pain, inflammation reactions, abscess formation or persistent discoloration of muscle tissue at the injection site as well as increased risk of bacterial disease. Furthermore, overdosing may lead to 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2012

15. OTHER INFORMATION

Uniferon is contained in hard plastic vial (HDPE), glass vial or collapsible vial (LDPE) in aluminium sachet.

The pack sizes are the following :
Hard plastic vial : 5 x 100 ml, 12 x 100 ml, 20 x 100 ml
Glass vial : 5 x 100 ml, 12 x 100 ml, 20 x 100 ml
Collapsible vial : 5 x 100 ml, 12 x 100 ml, 20 x 100 ml, 12 x 200 ml

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.