[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ursoferran 200 mg/ml solution for injection for pigs

(for United Kingdom and Hungary: Ferroferon 200 mg/ml; for Denmark: Viloferron 200 mg/ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Iron(III)-Ions 200.0 mg
as Gleptoferron 532.6 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5.0 mg
Water for injections	/

A dark brown, slightly viscous, sterile, colloidal, aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (piglets).

3.2 Indications for use for each target species

For prevention and treatment of iron deficiency anaemia in piglets.

3.3 Contraindications

Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in clinically diseased animals, especially not in case of diarrhoea.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

People with known hypersensitivity to iron dextran, or those with haemochromatosis should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection, as well as contact with the eyes and mouth.

In case of accidental injection seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs (piglets):

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site skin discolouration[1], injection site swelling[1,2]
Rare (1 to 10 animals / 10,000 animals treated):	Death[3]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity Death[4]

[1] Should disappear within a few days.
[2] Slight, soft.
[3] Associated with genetic factors or deficiency of vitamin E and/or selenium
[4] Attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.
See also section 5.1.

3.9 Administration routes and dosage

For strictly intramuscular use.

Piglets:
200 mg Fe^{3+} per animal which is equivalent to 1 ml of the product per animal.
Inject once between the 1st and the 3rd day of life.
The use of a multidose syringe is recommended. To refill the syringe use a draw-off needle to avoid excessive broaching of the stopper. The stopper must not be broached more than 10 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle has to be removed after treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 discolouration of muscle tissue at the injection site may occur.
Iatrogenic poisoning with 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QB03AC91

4.2 Pharmacodynamics

Iron is an essential micronutrient. It takes a major role in the oxygen transport of haemoglobin and myoglobin, as well as it has a key role in enzymes, such as cytochromes, catalases, and peroxidases. Iron has a high recovery rate from metabolism and food ingested. Thus, deficiency occurs only very rarely in adult animals.

4.3 Pharmacokinetics

After intramuscular injection, the iron complex is absorbed into the lymphatic tissue within 3 days. Here, the complex is split to release Fe^{3+} which is stored as ferritin in the main storage organs (e.g. liver, spleen and the reticuloendothelial system). In the blood, free Fe^{3+} binds to transferrin (transport form) and is mainly used for the synthesis of haemoglobin.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not freeze.

5.4 Nature and composition of immediate packaging

100 ml clear glass vial (type II), 100 ml LDPE bottle or 200 ml LDPE bottle with chlorobutyl rubber closure (type I) and aluminium/polypropylene cap.

Pack sizes:
Carton box with 1 glass vial with 100 ml
Carton box with 10 glass vials with 100 ml
Carton box with 10 LDPE bottles with 100 ml
1 LDPE bottle with 100 ml wrapped in plastic
Carton box with 10 LDPE bottles with 200 ml
1 LDPE bottle with 200 ml wrapped in plastic

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD month YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

Grey shaded text should only appear once on the packaging.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ursoferran 200 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Iron(III)-Ions 200.0 mg
as Gleptoferron 532.6 mg

3. PACKAGE SIZE

1 x 100 ml
10 x 100 ml
1 x 200 ml
10 x 200 ml

4. TARGET SPECIES

Pigs piglets

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For strictly intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG (logo)

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

vial/ bottle label

Grey shaded text should only appear once on the packaging.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ursoferran 200 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Iron(III)-Ions 200.0 mg
as Gleptoferron 532.6 mg

3. TARGET SPECIES

Pigs piglets

4. ROUTES OF ADMINISTRATION

For strictly intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days. Once broached, use by _____

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG (logo)

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ursoferran 200 mg/ml solution for injection for pigs

2. Composition

Each ml contains:

Active substance:

Iron(III)-Ions	200.0 mg
as Gleptoferron	532.6 mg

Excipients:

Phenol	5.0 mg

A dark brown, slightly viscous, sterile, colloidal, aqueous solution.

3. Target species

Pigs (piglets).

4. Indications for use

For prevention and treatment of iron deficiency anaemia in piglets.

5. Contraindications

Do not administer to piglets suspected to suffer from deficiency of vitamin E and /or selenium.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in clinically diseased animals, especially not in case of diarrhoea.

6. Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to iron dextran, or those with haemochromatosis should avoid contact with the product.
Care should be taken to avoid accidental self-injection, as well as contact with the eyes and mouth.
In case of accidental injection, seek medical advice immediately and show the package leaflet or label to the physician.
Wash hands after use.

Interaction with other medicinal products and other forms of interaction:
The absorption of concomitantly administered oral iron may be reduced.
See also under section “Major incompatibilities”.

Overdose:
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 discolouration of muscle tissue at the injection site may occur.
Iatrogenic poisoning with 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.

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

7. Adverse events

Pigs (piglets):

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site skin discolouration[1], injection site swelling[1,2]
Rare (1 to 10 animals / 10,000 animals treated):	Death[3]
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity Death[4]

[1] Should disappear within a few days.
[2] Slight, soft.
[3] Associated with genetic factors or deficiency of vitamin E and/or selenium
[4] Attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For strictly intramuscular use.

Piglets:
200 mg Fe^{3+} per animal which is equivalent to 1 ml of the product per animal.
Inject once between the 1st and the 3rd day of life.

The use of a multidose syringe is recommended. To refill the syringe use a draw-off needle to avoid excessive broaching of the stopper. The stopper must not be broached more than 10 times. When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle has to be removed after treatment.

9. Advice on correct administration

None.

10. Withdrawal periods

Meat and offal: Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

100 ml clear glass vial (type II), 100 ml LDPE bottle or 200 ml LDPE bottle with chlorobutyl rubber closure (type I) and aluminium/polypropylene cap.

Pack sizes:
Carton box with 1 glass vial with 100 ml
Carton box with 10 glass vials with 100 ml
Carton box with 10 LDPE bottles with 100 ml
1 LDPE bottle with 100 ml wrapped in plastic
Carton box with 10 LDPE bottles with 200 ml
1 LDPE bottle with 200 ml wrapped in plastic

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

Local representatives and contact details to report suspected adverse reactions: