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

Ferroferon 200 mg/ml
Solution for injection for pigs
Iron(III)-Ions (as Gleptoferron)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances:

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

Excipients:

Phenol	5.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pig piglet

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For strictly intramuscular injection.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Shelf-life after first opening: 28 days.

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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 - to be supplied only on veterinary prescription.

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

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
D-06406 Bernburg
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20631/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label

Grey shaded text should only appear once on the packaging.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ferroferon 200 mg/ml
Solution for injection for pigs
Iron(III)-Ions (as Gleptoferron)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substances:

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

Excipients:

Phenol	5.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Pig piglet

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For strictly intramuscular injection.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Shelf-life after first opening: 28 days.
Once broached, use by _____

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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

(not requested on the immediate label)

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

For animal treatment only - to be supplied only on veterinary prescription.

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

Serumwerk Bernburg AG
Hallesche Landstraße 105 b
D-06406 Bernburg
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20631/4002

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET

URSOFERRAN 200 mg/ml
Solution for injection for pigs

Ferroferon 200 mg/ml, Solution for injection for pigs

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

Marketing authorisation holder:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
D-06406 Bernburg
Germany

Manufacturer responsible for batch release:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

2. NAME OF THE VETERINARY MEDICINAL

PRODUCT URSOFERRAN 200 mg/ml
Solution for injection
for pigs Iron(III)-Ions
(as Gleptoferron)

Ferroferon 200 mg/ml, Solution

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

Each ml contains:

Active substances:

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.

4. INDICATION(S)

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 excipient(s).

Do not use in clinically diseased animals, especially not in case of diarrhoea.

6. ADVERSE REACTIONS

Uncommonly discolouration of the tissue and/or slight, soft swelling may be observed at the site of injection. This should disappear within a few days. Also hypersensitivity reactions can occur.

Rarely deaths have occurred in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.

Very rarely piglets deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}. For details regarding the national system please contact NCA.

7. TARGET SPECIES

Pig (piglet)

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

For strictly intramuscular injection.

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 PERIOD(S)

Meat and offal: Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children. Do not freeze.

Do not use after the expiry date stated on the label. Shelf-life after first opening the container: 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 WARNING(S)

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.

Use during pregnancy or lactation:
Not applicable

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

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 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.

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

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

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

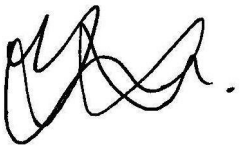
15. OTHER INFORMATION

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

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.

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



Approved: 06 December 2023