PARTICULARS TO APPEAR ON THE OUTER PACKAGE: Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ferroferon 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

Vm 20631/5001
Vm 20631/3001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE:
glass vial/LDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ferroferon 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}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Ferroferon 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
Water for injections	

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 excipient(s).
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.

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:
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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 20631/5001
Vm 20631/3001
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. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

Nutrapet Ltd.
Pexton House, Pexton Road
Kelleythorpe
Driffield
East Yorkshire
England
YO25 9FR
Email: Info@nutrapet.co.uk
Telephone:(+44) 1377 249249

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

17. Other information

POM-VPS

Gavin Hall
Approved: 04 March 2025