PACKAGE LEAFLET FOR

FERROFERON 200 mg/ml
Solution for injection for pigs

(For Denmark: Ursoglepto Vet. 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:
To be completed nationally

Manufacturing authorisation holder responsible for batch release:
Serumwerk Bernburg AG
Hallesche Landstraße 105 b
06406 Bernburg
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FERROFERON 200 mg/ml
Solution for injection for pigs

Iron(III)-Ions (as Gleptoferron)

(For Denmark: Ursoglepto Vet. 200 mg/ml, Solution for injection for pigs)

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 (preservative)	5.0 mg
Water for injections	ad 1 ml

4. INDICATION(S)

For prophylaxis 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 case 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. ADVERSE REACTIONS

Occasionally discolouration of the tissue and/or slight, soft swelling may be observed at the sight 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.

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD

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.

Shelf-life after first opening the immediate packaging: 28 days.
When the immediate packaging 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 immediate packaging 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:
Care should be taken to avoid accidental self-injection as well as mucous membrane contact, especially people with known hypersensitivity to iron dextran.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the 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

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.