**SUMMARY OF PRODUCT CHARACTERISTICS (SPC)**

## 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 substances:** | |
| Iron(III)-Ions | 200.0 mg |
| as Gleptoferron | 532.6 mg |
| **Excipients:** | |
| Phenol | 5.0 mg |

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for injection.
A dark brown, slightly viscous, sterile, colloidal, aqueous solution

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Pig (piglet)

### 4.2 Indications for use, specifying the target species

For prevention and treatment of iron deficiency anaemia in piglets.

### 4.3 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.

### 4.4 Special warnings for each target species

None

### 4.5 Special precautions for use

**Special precautions for use in animals:**

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 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.

## 4.6 Adverse reactions (frequency and seriousness)

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).

## 4.7 Use during pregnancy, lactation or lay

Not applicable

## 4.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.
See also section 6.2.

## 4.9 Amounts to be administered and administration route

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.

## 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 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.

### 4.11 Withdrawal period(s)

Meat and offal: Zero days

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron trivalent, parenteral preparations, gleptoferron

ATCvet Code: QB03AC91

### 5.1 Pharmacodynamic properties

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.

### 5.2 Pharmacokinetic particulars

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Phenol
Water for injections

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

### 6.4 Special precautions for storage

Do not freeze.

### 6.5 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.

### 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 products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

To be completed nationally

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

## 10 DATE OF REVISION OF THE TEXT

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable
To be supplied only on veterinary prescription.