[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTAFER 200 mg/ml solution for injection for pigs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Iron(III)..... 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.
Dark brown, slightly viscous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pig (piglet)

4.2 Indications for use, specifying the target species

For prophylaxis and treatment of iron deficiency anaemia in piglets.

4.3 Contraindications

Do not use in 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 the active substance (Iron dextran) or with hemochromatosis should avoid contact with the veterinary medicinal product.

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.

4.6 Adverse reactions (frequency and seriousness)

Discolouration of the tissue and/or slight, soft swelling may be observed at the site of injection uncommonly. This should disappear within a few days.
Hypersensitivity reactions can occur very rarely.
Deaths have occurred in piglets following the administration of parenteral iron dextran preparations rarely. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.
Piglets deaths which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial system have been reported in very rare occasions.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- 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 veterinary medicinal product per animal.
Inject once between the 1st and 3rd day of life.

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, haemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, oedema 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.
ATC vet code: QB03AC.

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: 4 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

Colourless, high density polyethylene (HDPE) vial with type I bromobutyl rubber stopper and aluminium cap.

Package size:
Carton box with 1 vial of 100 ml

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY
Date of last renewal: DD/MM/YYYY

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.