1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptovex 200 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Iron (III).....200.0 mg
(as Gleptoferron..... 532.6 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5.0 mg
Water for injections	

Dark brown, slightly viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs (piglets).

3.2 Indications for use for each target species

For the prevention and treatment of iron deficiency anaemia in piglets.

3.3 Contraindications

Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium.
Do not use in clinically diseased animals, especially not in cases of diarrhoea.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is advisable to stretch the skin at the injection site to minimize leakage after withdrawal of the needle. Observe aseptic precautions. Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to iron dextran (gleptoferron) or with hemochromatosis should avoid contact with the veterinary medicinal product.

Take care to avoid accidental self-injection and contact with mucous membranes. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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[3,4]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Hypersensitivity reaction

[1] Disappear within a few days.
[2] Mild.
[3] Associated with genetic factors or deficiency of vitamin E and/or selenium
[4] On very rare occasions 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.

3.9 Administration routes and dosage

For intramuscular use only.

The product is administered as a single 1 mL (200 mg iron) dose by deep intramuscular injection. 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.

Do not broach the 100 mL vial more than 20 times and a 200 mL vial more than 50 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Large amounts of iron administered by the parenteral route may result in transient reduced capacity of the immune system due to iron overload of lymph macrophages. Pain, inflammation reactions, abscess formation as well as persistent discolouration of muscle tissue at the injection site may occur.

Iatrogenic poisoning may result in the following signs: 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :QB03AC.

4.2 Pharmacodynamics

Iron is an essential micronutrient. It plays a major role in the oxygen transport of haemoglobin and myoglobin, as well as 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Polypropylene vial provided with a grey (100 ml) or pink (200 ml) bromobutyl rubber stopper and aluminium seal with a flip-off sealing.

Pack sizes:
Cardboard box with 1 vial of 100 ml.
Cardboard box with 1 vial of 200 ml.
Cardboard box with 10 vials of 100 ml.
Cardboard box with 10 vials of 200 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10790/010/001

8. DATE OF FIRST AUTHORISATION

02/12/2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

08/01/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).