1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptolab 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:

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, solution and slightly viscous. Free of visible sediment

3. CLINICAL INFORMATION

3.1. Target species

Pig (piglets).

3.2. Indications for use, for each target species

For the prevention and treatment of iron deficiency anaemia.

3.3. Contraindications

- Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
- Do not use in animals with hepatic and/or renal disease.
- 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.

3.4. Special warnings

None.

3.5. Special precautions for use

Special precautions for safe in the target species:
Normal aseptic injection techniques should be practised.
It is advisable to stretch the skin at the injection site to minimise leakage after withdrawal of the needle.

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.

Special precautions for the protection of the environment:
Not applicable.

3.6. Adverse events

Target species: Pigs (piglets)

Uncommon (1 to 10 animals / 1,000 animals treated):	Slight staining of muscle tissue at injection site Deaths [1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Deaths [2] Hypersensitivity reaction.

[1] have occurred in piglets following the administration of parenteral iron preparations. These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium
[2] in piglets, which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system, have been reported very rarely.

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 also the last section of 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

Do not mix with other products prior to administration.

3.9 Administration routes and dosage

Use only automatic syringe equipment. The product is administered as a single 1 ml (200 mg iron) dose by deep intramuscular injection into the hind limb midway between the stifle joint and the base of the tail.
Injections should be administered as follows:

For the prevention of iron deficiency anaemia: not later than the third day of life.

For the treatment of iron deficiency anaemia: at the onset of clinical anaemia normally within the first three weeks of life.

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

Over dosage with the product is unlikely to result in signs of intoxication.
In studies carried out in piglets with doses up to 6 times the recommended dose, no clinical signs of intolerance were observed, except for a slight staining of the muscle at the injection site, the intensity of which depends on the dose administered.

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: QBO3AC

4.2 Pharmacodynamic

Injectable iron-carbohydrate complexes are established haematinic agents in veterinary medicine. Following intramuscular injection, the complex is absorbed and metabolised to release the iron for utilisation and/or storage in accordance with the nutritional status of the animal. In iron deficient states, the iron is utilised for the synthesis of haemoglobin and other iron-containing molecules. Excess iron is stored principally in the liver (is stored in form of ferritin).

4.3 Pharmacokinetic

Absorption of the product has been shown to be rapid. Over 95% of the administered iron (1mL/200 mg iron administered at three days of age) was absorbed by 24 hours after injection.

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: 36 months
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

- High-density polyethylene collapsible bottles (HDPE) with a nominal capacity of 100 ml and 200 ml closed with a chlorobutyl rubber closure and an aluminium ring seal.
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Pack sizes:
Carton box with 1 bottle of 100 ml
Carton box with 10 bottles of 100 ml
Carton box with 20 bottles of 100 ml
Carton box with 40 bottles of 100 ml
Carton box with 1 bottle of 200 ml
Carton box with 10 bottles of 200 ml
Carton box with 20 bottles of 200 ml

Not all pack sizes may be marketed.

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

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

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10402/006/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.