1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptoferron Labiana 200 mg/ml Solution for Injection

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
Sodium chloride	
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.

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

The sachet in the low-density polyethylene collapsible bottles with a nominal capacity of 100 ml and 200 ml should not be opened until the veterinary medicinal product is required for use.

3.5. Special precautions for use

Special precautions for safe use in the target species:
Normal aseptic injection techniques should be practised.
Avoid the introduction of contamination during use.
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 hemochromatosis should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection as well as contact with the eyes, mouth and 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 change[1]
Rare (more than 1 but less than 10 animals in 10,000 animals treated):	Death[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death[3] Hypersensitivity reaction.

[1] Slight staining of muscle tissue.
[2] Associated with maternal dietary deficiency of vitamin E and/or selenium.
[3] 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

Do not mix with other products prior to administration.

3.9. Administration routes and dosage

Intramuscular use.

Use only automatic syringe equipment. The veterinary medicinal 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 veterinary medicinal product is unlikely to result in signs of intoxication.

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 Pharmacodynamics

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.

4.3 Pharmacokinetics

Absorption of the veterinary medicinal product has been shown to be rapid. Over 95% of the administered iron (1 ml/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: 3 years.
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

- Low-density polyethylene collapsible bottles (LDPE) with a nominal capacity of 100 ml and 200 ml closed with a chlorobutyl rubber closure and an aluminium ring seal. Each bottle is sealed in a sachet. The sachet is a polyester/polyethylene laminate. Do not open the sachet until ready to use the veterinary medicinal product.
- 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.

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 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

Labiana Life Sciences, S.A.

7. MARKETING AUTHORISATION NUMBER

8. 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 subject to prescription. [CY, EL, ES, PT, UK(NI)]

Veterinary medicinal product not subject to prescription. [IE]

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

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box of 100 ml HDPE bottle
Cardboard box of 200 ml HDPE bottle
Cardboard box of 100 ml LDPE bottle
Cardboard box of 200 ml LDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptoferron Labiana 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Iron (III)	200.0 mg
(as Gleptoferron	532.6 mg)

3. PACKAGE SIZE

1 x 100 ml
10 x 100 ml
20 x 100 ml
40 x 100 ml
1 x 200 ml
10 x 200 ml
20 x 200 ml

4. TARGET SPECIES

Pigs (piglets) 

5. INDICATIONS

For products not subject to veterinary prescription.
For the prevention and treatment of iron deficiency anaemia.

6. ROUTES OF ADMINISTRATION

i.m.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days.

8. EXPIRY DATE

Exp {month/year}
Shelf-life after first opening the container: 28 days

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

14. MARKETING AUTHORISATION NUMBERS

XXXXXX

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR THE IMMEDIATE PACKAGE
Label for 100 ml HDPE bottle
Label for 100 ml LDPE bottle
Label for 200 ml HDPE bottle
Label for 200 ml LDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptoferron Labiana 200 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Iron(III)	200.0 mg
(as Gleptoferron	532.6 mg)

3. TARGET SPECIES

Pigs (piglets)

4. ROUTES OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: zero days.

6. EXPIRY DATE

Exp {month/year}
Shelf life after first opening the container: 28 days

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Gleptoferron Labiana 200 mg/ml Solution for Injection

2. Composition

Active substance:

Iron(III)	200.0 mg/ml
(as Gleptoferron	532.6 mg)

Excipients:

Phenol	5 mg/ml

Dark brown, slightly viscous solution.

3. Target species

Pigs (piglets).

4. Indications for use

For the prevention and treatment of iron deficiency anaemia.

5. 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.

6. Special warnings

Special warnings:

The sachet in the low-density polyethylene collapsible bottles with a nominal capacity of 100 ml and 200 ml should not be opened until the veterinary medicinal product is required for use.

Special precautions for safe use in the target species:
Normal aseptic injection techniques should be practised.
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, or those with haemochromatosis should avoid contact with the veterinary medicinal product.
Care should be taken to avoid accidental self-injection, as well as contact with the eyes and mouth and mucous membranes.
In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Interaction with other medicinal products and other forms of interaction:
Do not mix with other products prior to administration.

Overdose:
Overdosage with the veterinary medicinal product is unlikely to result in signs of intoxication.

Major incompatibilities: None known.

7. Adverse events

Pigs (piglets):

Uncommon (1 to 10 animals / 1,000 animals treated):	Injection site skin change[1]
Rare (more than 1 but less than 10 animals in 10,000 animals treated)	Death[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death[3] Hypersensitivity reaction.

[1] Slight staining of muscle tissue.
[2] Associated with maternal dietary deficiency of vitamin E and/or selenium.
[3] 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use (**i.m.**).

Use only automatic syringe equipment.
The veterinary medicinal 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.

It is advisable to stretch the skin at the injection site to minimise leakage after withdrawal of the needle.

9. Advice on correct administration

Do not use the veterinary medicinal product if you notice visible signs of deterioration.

10. Withdrawal periods

Meat and offal: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.
This veterinary medicinal product does not require any special storage conditions.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. [CY, EL, ES, PT, UK(NI)]
Veterinary medicinal product not subject to prescription. [IE]

14. Marketing authorisation numbers and pack size

XXXXX

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Labiana Life Sciences, S.A.
Venus, 26. 08228 Terrassa
(Barcelona) Spain
Tel:+34 937369700

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information