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

Pig (piglets)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

i.m.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
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 SA

14. MARKETING AUTHORISATION NUMBERS

Vm 32112/4001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON 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

Pig (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. {mm/yyyy}
Shelf life after first opening the container: 28 days

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences SA

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE 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

Solution for injection
Dark, brown and slightly viscous solution.

3. Target species

Pig (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.

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.
In case of accidental injection, seek medical advice immediately and show the package leaflet or 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 NOS[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 at injection site
[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:
Website: https://www.gov.uk/report-veterinary-medicine-problem
e-mail: adverse.events@vmd.gov.uk

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 minimize 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.

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

To be supplied only on veterinary prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 32112/4001

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. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Labiana Life Sciences SA
Calle Venus 26
08228 Terrassa
Barcelona
Spain

Local representative and contact details to report suspected adverse reactions

Interchem (Ireland) Ltd
Unit 29
Cookstown Industrial
Estate
Dublin 24
Phone 01 451 8959
E-mail: SADR@interchem.ie

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

17. Other information

POM-VPS

Gavin Hall
Approved: 29 September 2026