

**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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gleptolab 200 mg/ml Solution for Injection for pigs

**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. ROUTE(S) OF ADMINISTRATION**

IM

**7. WITHDRAWAL PERIODS**

Withdrawal period:  
Meat and offal: zero days.

**8. EXPIRY DATE**

Exp {month/year}

Once broached, use by:.....

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  
Calle Venus 26  
E-08228 Terrassa  
Barcelona  
Spain

**14. MARKETING AUTHORISATION NUMBER(S)**

Vm 32112/3000

**17. BATCH NUMBER**

<Lot>{number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

100 ml and 200 ml HDPE bottle

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Gleptolab 200 mg/ml Solution for Injection for pigs

**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**

Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:  
Meat and offal: zero days.

**6. EXPIRY DATE**

Exp {month/year}  
Once broached use by....  
Shelf life after first opening the container: 28 days

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Labiana Life Sciences SA  
Calle Venus 26  
E-08228 Terrassa  
Barcelona  
Spain

**9. BATCH NUMBER**

Lot {number}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

**Gleptolab 200 mg/ml Solution for Injection for pigs**

### 2. Composition

**Active substance;**

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

**Excipients:**

Phenol	5 mg/ml
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Solution for injection

Dark, brown and slightly viscous solution. Free of visible sediment.

### 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 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:

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.

People with known hypersensitivity to iron dextran, or those with haemochromatosis should avoid contact with the product.



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 product is unlikely to result in signs of intoxication.

Special restrictions for use and special conditions for use:

Major incompatibilities: None known.

## 7. Adverse events

### Pigs (piglets)

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

<sup>1</sup>These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium.

<sup>2</sup> These deaths are 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 also the last section of the package leaflet for respective contact details.

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

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.

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 Gleptoferron Labiana 200mg/ml solution for injection if you notice visible signs of deterioration.

## **10. Withdrawal period**

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 how to dispose of medicines no longer required. These measures should help to protect the environment.

## **13. Classification of veterinary medicinal products**

To be supplied only on veterinary prescription

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

## **14. Marketing authorisation numbers and pack size**

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

**16. Contact details**

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

Labiana Life Sciences, S.A.  
Venus, 26. 08228 Terrassa  
(Barcelona) Spain

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

Approved 12 September 2023

