

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. PHARMACEUTICAL FORM

Solution for injection.

4. 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

5. TARGET SPECIES

Neonatal pigs.



6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Care should be taken to avoid accidental self-injection as well as contact with the eyes, mouth and mucous membranes, especially people with known hypersensitivity to iron dextran or those with haemochromatosis should avoid contact with the product.

In case of accidental injection, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

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

Avoid the introduction of contamination during use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use by:.....

Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABIANA Life Sciences, S.A.
C/Venus, 26 – 08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32112/4001

17. MANUFACTURER'S BATCH NUMBER

[<Batch><Lot> {number}]

PARTICULARS TO APPEAR THE IMMEDIATE PACKAGE

Label for 100 ml HDPE bottle
Label for 100 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. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES



6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Care should be taken to avoid accidental self-injection as well as contact with the eyes, mouth and mucous membranes, especially people with known

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

In case of accidental injection, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

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 product is required for use.

Avoid the introduction of contamination during use.

10. EXPIRY DATE

EXP {month/year}

Once opened use by:....

Shelf life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABIANA Life Sciences, S.A.
C/Venus, 26 – 08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32112/4001

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

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. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

200 ml.

5. TARGET SPECIES

Neonatal pigs.



6. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Care should be taken to avoid accidental self-injection as well as contact with the eyes, mouth and mucous membranes, especially people with known hypersensitivity to iron dextran or those with haemochromatosis should avoid contact with the product.

In case of accidental injection, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

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

Avoid the introduction of contamination during use.

10. EXPIRY DATE

EXP {month/year}

Once broached, use by:.....

Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABIANA Life Sciences, S.A.
C/Venus, 26 – 08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32112/4001

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Gleptoferron Labiana 200 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

LABIANA Life Sciences, S.A.

C/Venus, 26 – 08228 Terrassa (Barcelona).Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptoferron Labiana 200 mg/ml Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Dark, brown slightly viscous solution for injection.

Active substance;

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

Excipients:

Phenol 5 mg/ml

4. INDICATION(S)

For the prevention and treatment of iron deficiency anaemia.

5. CONTRAINDICATIONS

Do not use in case of:

- Hypersensitivity to gleptoferron complex or any of the excipients.
- 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 case of diarrhoea.

6. ADVERSE REACTIONS

Slight staining of muscle tissue may occur uncommonly at the injection site. Deaths have rarely 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.

Deaths 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.

Hypersensitivity reactions have been reported very rarely in spontaneous reports.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals).
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details.

7. TARGET SPECIES

Neonatal pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Use only automatic syringe equipment.

Swab the septum before use. 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.

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

Shelf life after first opening the container: 28 days

Do not use this veterinary medicinal product after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Special precautions for use in animals

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 product.

Care should be taken to avoid accidental self-injection as well as contact with the eyes, mouth and mucous membranes, especially people with known hypersensitivity to iron dextran. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after use.

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 product is required for use.

Interaction with other medicinal products and other forms of interaction:

There are no known interactions between the product and other medicaments. There are no known other forms of interaction. Do not mix with other products prior to administration.

Overdose (symptoms, emergency procedures, antidotes): Overdosage with the product is unlikely to result in signs of intoxication.

Incompatibilities: None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

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

These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2022

15. OTHER INFORMATION

- 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.

Carton box with 1, 10 20, or 40 bottles of 100 ml or 1, 10 or 20 bottles of 200 ml.

Not all pack sizes may be marketed.

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

Approved 09 March 2022

