

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

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

GLEPTOVEX 200 mg/ml solution for injection for pigs  
Iron III (as Gleptoferron)

**2. STATEMENT OF ACTIVE SUBSTANCES**

**Active substance:**

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

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

Vial 100 ml  
Vial 200 ml  
Box 1x100 ml  
Box 1x200 ml  
Box 10x100 ml  
Box 10x200 ml

**5. TARGET SPECIES**

Pigs (piglets)

**6. INDICATION(S)**

*Only for those countries where the product is available without prescription.*  
For the prevention and treatment of iron deficiency anaemia in piglets.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Meat and offal: Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

## **10. EXPIRY DATE**

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.

Once opened, use by...

BOX: PL: Termin ważności (EXP)

## **11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

## **12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: read package leaflet.

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

For animal treatment only.

BOX IT:  
REGIME DI DISPENSAZIONE  
RICETTA IN COPIA UNICA NON RIPETIBILE

BOX PL:  
Wyłącznie dla zwierząt

Wydawany z przepisu lekarza – Rp.

Do podawania pod nadzorem lekarza weterynarii.

BOX UK:  
To be supplied only on veterinary prescription, POM-VPS

## **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**

SP Veterinaria SA  
Ctra Reus Vinyols km 4.1  
43330 Riudoms  
España (Spain)

**16. MARKETING AUTHORISATION NUMBER**

Vm 36967/4007

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

BOX PL: Nr serii (Lot)

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

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

GLEPTOVEX 200 mg/ml solution for injection for pigs  
Iron III (as Gleptoferron)

**2. STATEMENT OF ACTIVE SUBSTANCES**

Active substance:  
Iron (III) 200.0 mg  
(as Gleptoferron 532.6 mg)

**3. PHARMACEUTICAL FORM**

Solution for injection.

**4. PACKAGE SIZE**

Vial 100 ml  
Vial 200 ml  
Box 1x100 ml  
Box 1x200 ml  
Box 10x100 ml  
Box 10x200 ml

**5. TARGET SPECIES**

Pigs (piglets)

**6. INDICATION(S)**

Read the package leaflet before use.

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD**

Withdrawal period: Meat and offal: Zero days

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Shelf life after first opening the immediate packaging: 28 days.

Once opened, use by...

**11. SPECIAL STORAGE CONDITIONS**

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

**12. SPECIFIC 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.

UK: To be supplied only on veterinary prescription, POM-VPS

**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**

SP Veterinaria SA  
Ctra Reus Vinyols km 4.1  
43330 Riudoms  
España (Spain)

**16. MARKETING AUTHORISATION NUMBER**

Vm 36967/4007

**17. MANUFACTURER'S BATCH NUMBER**

Batch {number}

PL: Nr.Serii

## **B. PACKAGE LEAFLET**



**PACKAGE LEAFLET:**

**GLEPTOVEX 200 mg/ml solution for injection for pigs**

**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:

SP VETERINARIA SA  
Ctra Reus Vinyols km 4.1  
43330 Riudoms  
España (Spain)

Manufacturer responsible for batch release:

CENAVISA, S.L.  
Cami Pedra Estela s/n  
43205 Reus  
España (Spain)

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

GLEPTOVEX 200 mg/ml solution for injection for pigs  
Iron (III) (as Gleptoferron)

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

Each ml contains:

**Active substance:**

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

**Excipients:**

Phenol	5.0 mg
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Dark brown, slightly viscous solution.

**4. INDICATION(S)**

For the prevention and treatment of iron deficiency anaemia in piglets.

**5. CONTRAINDICATIONS**

Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in clinically diseased animals, especially not in cases of diarrhoea.

## 6. ADVERSE REACTIONS

Discolouration of the tissue and/or slight, soft swelling may be observed uncommonly at the site of injection. This should disappear within a few days. Also hypersensitivity reactions can occur.

Deaths have occurred rarely in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.

Piglet deaths which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system have been reported very rarely.

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

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

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

Alternatively you can report via your national system.

## 7. TARGET SPECIES

Pigs (piglets)

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

For intramuscular use only.

*Piglets:*

The product is administered as a single 1 mL (200 mg iron) dose by deep intramuscular injection. Inject once between the 1<sup>st</sup> and the 3<sup>rd</sup> day of life.

The use of a multidose syringe is recommended. To refill the syringe use a draw-off needle to avoid excessive broaching of the stopper.

Do not broach the 100 ml vial more than 20 times and a 200 ml vial more than 50 times.

## 9. ADVICE ON CORRECT ADMINISTRATION

## 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.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Shelf life after first opening the container: 28 days.

## **12. SPECIAL WARNING(S)**

### Special precautions for use in animals:

It is advisable to stretch the skin at the injection site to minimize leakage after withdrawal of the needle. Observe aseptic precautions. 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 the active substance (gleptoferron) or with hemochromatosis should avoid contact with the veterinary medicinal product.

Take care to avoid accidental self-injection and contact with 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.

### Interaction with other medicinal products and other forms of interaction:

The absorption of concomitantly administered oral iron may be reduced.

### Overdose (symptoms, emergency procedures, antidotes):

Large amounts of iron administered by the parenteral route may result in transient reduced capacity of the immune system due to iron overload of lymph macrophages. Pain, inflammation reactions, abscess formation as well as persistent discolouration of muscle tissue at the injection site may occur.

Iatrogenic poisoning may result in the following signs: pale mucous membranes, haemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, oedema of the limbs, lameness, shock, death, liver damage. Supportive measures such as chelating agents can be used.

### Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

#### 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

#### 15. OTHER INFORMATION

Polypropylene vials of 100 ml and 200 ml nominal fill volume, provided with a grey (100 ml) or pink (200 ml) bromobutyl rubber stopper and aluminium seal with a Flip-off sealing.

Pack sizes:

Box with 1 vial of 100 ml

Box with 1 vial of 200 ml

Box with 10 vials of 100 ml

Box with 10 vials of 200 ml

Not all pack sizes may be marketed.

IE: LM Licensed Merchant

PL: Wyłącznie dla zwierząt

Wydawany z przepisu lekarza – Rp.

Do podawania pod nadzorem lekarza weterynarii.

UK:

For Animal Treatment Only

To be supplied only on veterinary prescription: POM-VPS

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

Approved 02 November 2023

