# 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
Riudoms ( 43330)
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 |

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 1st and the 3rd 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

## 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.