*[Version 9, 03/2022] corr. 11/2022*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTAFER 200 mg/ml solution for injection for pigs.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

**Excipients:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Phenol | 5.0 mg |
| Water for injections | |

Dark brown, slightly viscous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pig (piglet)

### 3.2 Indications for use for each target species

For prophylaxis and treatment of iron deficiency anaemia in piglets.

### 3.3 Contraindications

Do not use in 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 case of diarrhoea.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to the active substance (Iron dextran) or with hemochromatosis 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 self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

*Pigs:*

| | |
|---|---|
| *Uncommon*<br>*(1 to 10 animals / 1,000 animals treated):* | *Injection site skin discolouration*[1]<br>*Injection site swelling*[1] |
| *Rare*<br>*(1 to 10 animals / 10,000 animals treated):* | *Death*[2] |
| *Very rare*<br>*(<1 animal / 10,000 animals treated, including isolated reports):* | *Hypersensitivity reaction* |

*[1] Slight, soft. These reactions should disappear within a few days.*
*[2]In rare occasions, associated with genetic factors or deficiency of vitamin E and/or selenium and, in very rare occasions, attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial 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 the package leaflet for respective contact details.*

### 3.7 Use during pregnancy, lactation or lay

Not applicable.

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

The absorption of concomitantly administered oral iron may be reduced.

### 3.9 Administration routes and dosage

For strictly intramuscular injection.

*Piglets:*
200 mg $Fe^{+3}$ per animal which is equivalent to 1 ml of the veterinary medicinal product per animal.
Inject once between the 1st and 3rd day of life.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

Transferrin-iron saturation levels leading to increased susceptibility for (systemic) bacterial disease, pain, inflammation reactions as well as abscess formation at the injection site may occur.
Persistent discolouration of muscle tissue at the injection site may occur.
Iatrogenic poisoning with following symptoms: 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.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

<To be completed nationally>

### 3.12 Withdrawal periods

Meat and offal: Zero days.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QB03AC.

### 4.2 Pharmacodynamics

Iron is an essential micronutrient. It takes a major role in the oxygen transport of haemoglobin and myoglobin, as well as it has a key role in enzymes, such as cytochromes, catalases, and peroxidases.
Iron has a high recovery rate from metabolism and food ingested. Thus, deficiency occurs only very rarely in adult animals.

### 4.3 Pharmacokinetics

After intramuscular injection, the iron complex is absorbed into the lymphatic tissue within 3 days. Here, the complex is split to release $Fe^{3+}$ which is stored as ferritin in the main storage organs (e.g. liver, spleen and the reticuloendothelial system). In the blood, free $Fe^{3+}$ binds to transferrin (transport form) and is mainly used for the synthesis of haemoglobin.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after first opening the immediate packaging: 28 days.

### 5.3. Special precautions for storage

Do not freeze.

### 5.4 Nature and composition of immediate packaging

Colourless, high density polyethylene (HDPE) vial with type I bromobutyl rubber stopper and aluminium cap.

Package size:
Carton box with 1 vial of 100 ml

### 5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

DD/MM/YYYY

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX/100 ml vial**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTAFER 200 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

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

## 3. PACKAGE SIZE

100 ml

## 4. TARGET SPECIES

Pig (piglet).

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

For strictly intramuscular injection.

## 7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

## 8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days

Once broached use by…

## 9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

## 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

Laboratorios SYVA S.A.

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**{Label/100 ml vial}**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTAFER 200 mg/ml solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

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

## 3. TARGET SPECIES

Pig (piglet).

## 4. ROUTES OF ADMINISTRATION

For strictly intramuscular injection.
Read the package leaflet before use.

## 5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: Zero days.

## 6. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 28 days

## 7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

## 9. BATCH NUMBER

Lot {number}

**B. PACKAGE LEAFLET**

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

GLEPTAFER 200 mg/ml solution for injection for pigs.

## 2. Composition

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.

## 3. Target species

Pig (piglet)

## 4. Indications for use

For prophylaxis and treatment of iron deficiency anaemia in piglets.

## 5. Contraindications

Do not use in 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 case of diarrhoea.

## 6. Special warnings

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to the active substance (Iron dextran) or with hemochromatosis 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 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:
Transferrin-iron saturation levels leading to increased susceptibility for (systemic) bacterial disease, pain, inflammation reactions as well as abscess formation at the injection site may occur.
Persistent discolouration of muscle tissue at the injection site may occur.

Iatrogenic poisoning with following symptoms: 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.

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

Special restrictions for use and special conditions for use.
<To be completed nationally>

## 7. Adverse events

Pigs:

| |
|---|
| *Uncommon*<br>*(1 to 10 animals / 1,000 animals treated):* |
| *Injection site skin discolouration*[1]<br>*Injection site swelling*[1] |
| *Rare*<br>*(1 to 10 animals / 10,000 animals treated):* |
| *Death*[2] |
| *Very rare*<br>*(<1 animal / 10,000 animals treated, including isolated reports):* |
| *Hypersensitivity reaction* |

[1] Slight, soft. These reactions should disappear within a few days.
[2]In rare occasions, associated with genetic factors or deficiency of vitamin E and/or selenium and, in very rare occasions, attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial 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 the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

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

For strictly intramuscular injection.

*Piglets*:
200 mg $Fe^{+3}$ per animal which is equivalent to 1 ml of the veterinary medicinal product per animal.
Inject once between the 1st and 3rd day of life.

## 9. Advice on correct administration

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

## 10. Withdrawal periods

Meat and offal: Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

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

Shelf life after first opening the container: 28 days.

## 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 or pharmacist how to dispose of medicines no longer required.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Package size:
Carton box with 1 vial of 100 ml

## 15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

## 16. Contact details

Marketing authorisation holder:

Laboratorios Syva, S.A.
Calle Marqués de la Ensenada, 16
28004 MADRID
ESPAÑA

Manufacturer responsible for batch release:

Laboratorios Syva, S.A.
Avenida del Párroco Pablo Díez, 49-57
San Andrés del Rabanedo
24010 LEÓN
ESPAÑA

Local representatives and contact details to report suspected adverse reactions:

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

**España**
Contact details to report suspected adverse reactions:
Laboratorios Syva, S.A.
Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 34 987 800 800
E-mail: farmacovigilancia@syva.es

**Polska**
Local representative:
Biowet Drwalew Sp. z o.o.
Tel.: +48 691 014 430
Contact details to report suspected adverse reactions:
Biowet Drwalew Sp. z o.o.
Tel.: +48 691 014 430
E-mail : dzialania.niepozadane@biowet-drwalew.pl

**Portugal**
Contact details to report suspected adverse reactions:
Laboratorios Syva, S.A.
Parque Tecnológico de León
Calle Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
Tel: + 351 219 747 934
E-mail: syva.portugal@syva.pt

**România**
Contact details to report suspected adverse reactions:
DEAVET Srl
Tel: +40722347218
E-mail: toni@deavet.ro