[Version 8.1,01/2017]

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

Active substance:

Iron(III)-Ions ..... 200.0 mg

as Gleptoferron ..... 532.6 mg

Excipients:

Phenol ..... 5.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Dark brown, slightly viscous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Pig (piglet).

4.2 Indications for use, specifying the target species

For prophylaxis and treatment of iron deficiency anaemia in piglets.

4.3 Contraindications

Do not use in piglets suspected to suffer from deficiency of vitamin E and/or selenium.

Do not use in case 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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 mucous membrane contact, especially people with known hypersensitivity to iron dextran.

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.

4.6 Adverse reactions (frequency and seriousness)

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

Rarely deaths have occurred 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. Very rarely piglets deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial system.

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 reports).

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.

See also section 6.2.

4.9 Amounts to be administered and administration route

For strictly intramuscular injection.

Piglets:

200 mg Fe^{+3} per animal which is equivalent to 1 ml of the product per animal.

Inject once between the 1st and 3rd day of life.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron trivalent, parenteral preparations.

ATC vet code: QB03AC.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol

Water for injections

6.2 Major incompatibilities

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

6.3 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.

6.4. Special precautions for storage

Do not freeze.

6.5 Nature and composition of immediate packaging

Colourless, high density polyethylene (HDPE) vial of 100 ml with type I bromobutyl rubber stopper and aluminium cap.

Pack size:

Carton box with 1 vial of 100 ml

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

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

7. MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

Tel: 0034 987800800
Fax: 0034 987802452
Email: mail@syva.es

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

Date of last renewal:

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

To be supplied only on veterinary prescription.

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 for pigs

Gleptoferron

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Iron(III)-Ions ..... 200.0 mg

as Gleptoferron ..... 532.6 mg

Phenol ..... 5.0 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pig (piglet).

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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}

Once opened use within 28 days

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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. To be supplied only on veterinary prescription.

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

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

Tel. 0034 987800800
Fax: 0034 987802452
e-mail: mail@syva.es

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {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 for pigs

Gleptoferron

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Iron(III)-Ions ..... 200.0 mg

as Gleptoferron ..... 532.6 mg

Phenol ..... 5.0 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pig (piglet).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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}

Once opened use within 28 days

11. SPECIAL STORAGE CONDITIONS

Do not freeze.

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. To be supplied only on veterinary prescription.

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

Laboratorios SYVA S.A.U.
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Spain

Tel. 0034 987800800
Fax: 0034 987802452
e-mail: mail@syva.es

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

GLEPTAFER 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:

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTAFER 200 mg/ml solution for injection for pigs.

Gleptoferron

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

Each ml contains:

Iron(III)-Ions ..... 200.0 mg

as Gleptoferron ..... 532.6 mg

Phenol ..... 5.0 mg

Solution for injection.

Dark brown, slightly viscous solution.

4. INDICATION(S)

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 case 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. ADVERSE REACTIONS

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

Rarely deaths have occurred 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. Very rarely piglets deaths have been reported which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial system.

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- 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 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.

7. TARGET SPECIES

Pig (piglet).

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

For strictly intramuscular injection.

Piglets:

200 mg Fe^{+3} per animal which is equivalent to 1 ml of the product per animal.

Inject once between the 1st and 3rd day of life.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Not applicable.

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 mucous membrane contact, especially people with known hypersensitivity to iron dextran.

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):

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.

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

Medicines should not be disposed of via wastewater or household waste

Ask your veterinary surgeon or pharmacist 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

DD/MM/YYYY

15. OTHER INFORMATION

Pack size:

Carton box with 1 vial of 100 ml