[Version 8.2,01/2021]

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.
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 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. ADVERSE REACTIONS

Discolouration of the tissue and/or slight, soft swelling may be observed at the site of injection uncommonly. This should disappear within a few days.
Hypersensitivity reactions can occur very rarely.
Deaths have occurred in piglets following the administration of parenteral iron dextran preparations rarely. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.
Piglets deaths which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendotelial system have been reported in very rare occasions.

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).

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

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 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 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. The expiry date refers to the last day of that month.

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:
People with known hypersensitivity to the active substance (Iron dextran) or with hemochromatosis should avoid contact with the veterinary medicinal product.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

Package size:
Carton box with 1 vial of 100 ml