ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previron 200 mg/ml solution for injection
iron (III) (as gleptoferron)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains iron (III) 200 mg (as gleptoferron 532.6 mg)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: Zero days.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first broaching the container: 28 days.
Once broached use by …

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL 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.

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 HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/4017

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{GLASS VIAL LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previron 200 mg/ml solution for injection
iron (III) (as gleptoferron)

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains iron (III) 200 mg (as gleptoferron 532.6 mg)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Pigs (piglets)

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: Zero days.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first broaching the container: 28 days.
Once broached use by …

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL 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.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/4017

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Previron 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 Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previron 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

Solution for injection.
Dark brown, slightly viscous solution.

4. INDICATION(S)

For the prevention 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.
Do not use in clinically diseased animals, especially not in case of diarrhoea.
Do not administer intravenously.

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. Hypersensitivity reactions can occur. Deaths in piglets following the administration of parenteral iron

dextran preparations associated with genetic factors or deficiency of vitamin E and/or selenium have been reported rarely.
Deaths in piglets 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 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

Pigs (piglets).

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

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.

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. The stopper must not be broached more than 10 times.
When treating groups of animals in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle has to be removed after treatment.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 28 days.

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 container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals
Normal aseptic injection techniques should be practised. Avoid the introduction of contamination during use.
It is advisable to stretch the skin at the injection site to minimise leakage after withdrawal of the needle.

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), if necessary
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..
Poisoning arising from treatment may result in the following signs: pale mucous membranes, haemorrhagic gastroenteritis, vomiting, rapid heart rate, hypotension, breathlessness, oedema of the limbs, lameness, shock, death, liver damage.
Supportive measures such as chelating agents can be used.
Iron overdose can result in gastrointestinal signs such as diarrhoea or constipation.
Treat symptomatically.

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 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

September 2021

15. OTHER INFORMATION

Pack sizes:
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml

Not all pack sizes may be marketed.

Approved: 12/11/21