SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Previron 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:
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

Pigs (piglets)

4.2 Indications for use, specifying the target species

For the prevention 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 cases of hypersensitivity to the active substance.
Do not use in clinically diseased animals, especially not in case of diarrhoea.
Do not administer intravenously.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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

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. 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)

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.

4.9 Amounts to be administered and administration route

Intramuscular use.

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. 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.

4.10 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.
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.
Iron overdose can result in gastrointestinal signs such as diarrhoea or constipation.
Treat symptomatically.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron, parenteral preparations.
ATC vet code: QB03AC

5.1 Pharmacodynamic properties

Iron is an essential micronutrient. It plays a major role in the oxygen transport of haemoglobin and myoglobin, as well as 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

100 ml and 250 ml amber Type II glass vials, closed with Type I polymeric elastomer stopper with aluminium cap.

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

Not all pack sizes may be marketed.

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

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8. MARKETING AUTHORISATION NUMBER

Vm 17533/4017

9. DATE OF FIRST AUTHORISATION

09 November 2016

10. DATE OF REVISION OF THE TEXT

November 2021

Approved: 12/11/21