SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptoferron Labiana 200 mg/ml Solution for Injection

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.
A dark brown, slightly viscous, sterile, colloidal, aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Neonatal pigs.

4.2 Indications for use, specifying the target species

For the prevention and treatment of iron deficiency anaemia.

4.3 Contraindications

Do not use in case of:

- Hypersensitivity to gleptoferron complex or any of the excipients.
- In animals with hepatic and/or renal disease.
- Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium.
- Do not use in clinically diseased animals, especially not in case of diarrhoea.

4.4 Special warnings for each target species

The sachet in the low-density polyethylene collapsible bottles with a nominal capacity of 100 ml and 200 ml should not be opened until the product is required for use.

4.5 Special precautions for use

i) 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 minimize leakage after withdrawal of the needle.

ii) 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 as well as contact with the eyes, mouth and 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)

*S*light staining of muscle tissue may occur uncommonly at the injection site.
Deaths have rarely occurred in piglets following the administration of parenteral iron preparations. These deaths have been associated with maternal dietary deficiency of vitamin E and/or selenium.
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.
Hypersensitivity reactions have been reported very rarely in spontaneous reports.

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

There are no known interactions between the product and other medicaments. There are no known other forms of interaction. Do not mix with other products prior to administration.

4.9 Amount to be administered and administration route

Use only automatic syringe equipment. Swab the septum before use. The product is administered as a single 1 ml (200 mg iron) dose by deep intramuscular injection into the hind limb midway between the stifle joint and the base of the tail. Injections should be administered as follows:

For the prevention of iron deficiency anaemia: not later than the third day of life.

For the treatment of iron deficiency anaemia: at the onset of clinical anaemia normally within the first three weeks of life.

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

Over dosage with the product is unlikely to result in signs of intoxication.

4.11 Withdrawal period

Meat and offal: zero days.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: QBO3AC
Pharmacotherapeutic group: Antianaemic preparations, Iron preparations, Iron trivalent, parenteral preparations

5.1. Pharmacodynamic properties

Injectable iron-carbohydrate complexes are established haematinic agents in veterinary medicine. Following intramuscular injection, the complex is absorbed and metabolised to release the iron for utilisation and/or storage in accordance with the nutritional status of the animal. In iron deficient states, the iron is utilised for the synthesis of haemoglobin and other iron-containing molecules. Excess iron is stored principally in the liver.

5.2. Pharmacokinetic particulars

Absorption of the product has been shown to be rapid. Over 95% of the administered iron (1mL/200 mg iron administered at three days of age) was absorbed by 24 hours after injection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium chloride
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 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

- Low-density polyethylene collapsible bottles (LDPE) with a nominal capacity of 100 ml and 200 ml closed with a chlorobutyl rubber closure and an aluminium ring seal. Each bottle is sealed in a sachet. The sachet is a polyester/polyethylene laminate. Do not open the sachet until ready to use the veterinary medicinal product.
- High-density polyethylene collapsible bottles (HDPE) with a nominal capacity of 100 ml and 200 ml closed with a chlorobutyl rubber closure and an aluminium ring seal.

Carton box with 1, 10 20, or 40 bottles of 100 ml or 1, 10 or 20 bottles of 200 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Labiana Life Sciences S.A.
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Can Parellada Industrial
08228 Terrassa
Barcelona
Spain

8. MARKETING AUTHORISATION NUMBER

Vm 32112/4001

9. DATE OF FIRST AUTHORISATION

24 October 2017

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 09 March 2022