SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Gleptosil 200mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Iron	200 mg/ml
(as gleptoferron complex).	498 mg/ml)

Excipients:

Phenol	5 mg/ml

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

Neonatal pigs:
For the prevention and treatment of iron deficiency anaemia.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i) Special precautions for use in animals

Normal aseptic injection techniques should be practised.

ii) Special precautions for the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self injection. In the event of accidental self injection seek medical advice. Wash hands after use.

iii) Other precautions

The sachet should not be opened until the product is required for use.
Avoid the introduction of contamination during use.

4.6 Adverse reactions (frequency and seriousness)

There are normally no undesirable side effects associated with the use of the product. Its use does not result in permanent staining of the injected muscle tissue.

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.
For 100 & 250 ml plastic vials: as the vial cannot be broached more than 20 times, use of automatic syringe equipment is recommended.
For 100 ml collapsible vial: as the vial cannot be broached more than 4 times, the use of automatic syringe equipment is recommended.

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

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

4.11 Withdrawal period

MEAT AND OFFAL: ZERO DAYS.

5. PHARMACOLOGICAL PROPERTIES

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

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 properties

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. Use of the product does not result in permanent staining of the injected muscle tissue.

5.3 Environmental properties

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Phenol
Sodium chloride
Water for injections

6.2. Major incompatibilities

None known

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale in 100 ml collapsible vial: 2 years.
Shelf life after opening the immediate packaging: 28 days Shelf-life of the veterinary medicinal product as packaged for sale in 100 & 250 ml multilayer plastic vials: 3 years.

6.4. Special precautions for storage

Do not store above 25°C. Protect from light.

6.5. Nature and composition of immediate packaging

100 mL clear colourless low-density polyethylene collapsible bottles with grey chlorbutyl rubber bung with aluminium overseal.

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

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

Ceva Animal Health Ltd
Explorer House
Mercury Park
Wycombe Lane
Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom

8. MARKETING AUTHORISATION NUMBER

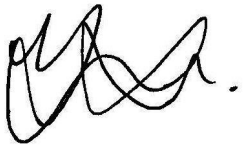
Vm 15052/4079

9. DATE OF FIRST AUTHORISATION

30 August 1995

10. DATE OF REVISION OF THE TEXT

October 2022



Approved: 06 October 2022