SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovifer 200 mg/ml, solution for injection, cattle (calves)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Iron(III) 200 mg
(as Iron(III) hydrogenated dextran complex).
Equivalent to 519 mg of iron dextran complex.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium chloride	
Phenol	5 mg
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid diluted (for pH adjustment)	
Water for injections	

Dark brown, non transparent solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves).

3.2 Indications for use for each target species

Prevention and treatment of iron deficiency anaemia in calves.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In sensitive individuals iron dextran may cause anaphylactic reactions after injection. Care should be taken to avoid self-injection, especially people with known hypersensitivity to iron dextran or any of the excipients. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Iron dextrans have been shown to be teratogenic and embryocidal in animal studies. The veterinary medicinal product should not be administered by pregnant women or women planning to be pregnant due to the risk of accidental self-injection. Accidental self-injection of iron dextran may also cause exacerbation of inflammatory synovitis in affected joints in anaemic rheumatoid patients.
The veterinary medicinal product may cause skin and eye irritation.
Avoid contact with skin, mucous membranes and eyes.
Accidental spillage onto skin or into the eyes should be thoroughly rinsed with water.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle (calves): Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction, Injection site skin discolouration[1]

[1]Transient discoloration and calcifications at the injection site.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.

1000 mg of iron per calf corresponding to 5 ml per calf at 1-10 days of age.

If needed, treatment may be repeated once after a minimum of 8 days. The need for a second injection should be determined by e.g. haemoglobin screening.

When treating groups of animals in one run, a multiple dose syringe and a draw-off needle must be used to avoid excess broaching of the stopper. The draw-off needle has to be removed after treatment. The stopper may be safely punctured up to 4 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 discoloration of muscle tissue at the injection site may occur.

- Iatrogenic poisoning with the following symptoms: pale mucous membranes, hemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, edema of the limbs, lameness, shock, death, liver damage. Supportive measures such as chelating agents can be used.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QB03AC

4.2 Pharmacodynamics

Iron is an essential component of haemoglobin in the erythrocytes transporting oxygen to all parts of the body. The veterinary medicinal product contains iron as a stable iron(III)-hydroxide dextran complex, which is analogous to the physiological form of iron, ferritin (ferric hydroxide phosphate protein complex). The iron is available in a non-ionic water-soluble form that has a very low toxicity compared to free iron. Iron (as iron dextran) is antianaemic by increasing the reserve in iron that is necessary for the formation of haemoglobin and the refill of enzymes linked to iron and involved in growth and resistance to infections. After administration, the ferri hydroxide dextran complex is deposited in the reticuloendothelial system, and then iron is progressively released from the complex.

4.3 Pharmacokinetics

After intramuscular injection, iron dextran is absorbed rapidly from the injection site into the capillaries and the lymphatic system. Circulating iron is removed from the plasma by cells of the reticuloendothelial system which split the complex into its components of iron and dextran. The iron is immediately bound to the available protein moieties to form haemosiderin or ferritin, the physiological forms of iron, or to a lesser extent, to transferrin. The plasma half life is 5 hours for circulating iron. Small quantities of iron are eliminated in urine and faeces.
Dextran is either metabolised or excreted.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 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 if stored below 25°C.

5.3 Special precautions for storage

Do not store above 30°C.
Do not open the aluminium foil before use of the LDPE vial.
After first opening the immediate packaging store below 25ºC.

5.4 Nature and composition of immediate packaging

100 ml clear type II glass vial with chlorobutyl rubber stopper and aluminium cap.
100 ml or 200 ml LDPE vial with chlorobutyl rubber stopper and aluminium cap in an aluminium sachet.

Pack sizes:
Carton box with 1, 5, 10, 12, 20, 48 glass vials of 100 ml.
Carton box with 1, 5, 10, 12, 20, 48 LDPE vials of 100 ml or 1, 5, 12 LDPE vials of 200 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

7. MARKETING AUTHORISATION NUMBER

To be completed nationally

8. DATE OF FIRST AUTHORISATION

To be completed nationally

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

2024-12-11

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription: BE, FR, DE, IT, NL, PL, ES and SE
Veterinary medicinal product not subject to prescription: DK and IE

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).