PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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:
5 mg phenol as a preservative

Dark brown, non transparent solution for injection.

3. Target species

Cattle (calves)

4. Indications for use

Prevention and treatment of iron deficiency anemia in calves.
The veterinary medicinal product contains a complex of iron which rapidly transfers the iron to storage deposits in the liver, spleen and bone marrow. The injection results in a rapid increase of hemoglobin and hematocrit parameters.

5. Contraindications

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

6. Special warnings

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.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
Overdosing with parenteral iron dextran may lead to an increased susceptibility to (systemic) bacterial disease, pain, inflammation reactions, persistent discoloration of muscle tissue and abscess formation at the injection site. Furthermore, overdosing may lead to iatrogenic poisoning with the following possible 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.

7. 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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

The veterinary medicinal product can be injected intramuscularly.

10. Withdrawal periods

Meat and offal: Zero days.

11. Special storage precautions

Do not store above 30°C.
Keep out of the sight and reach of children.
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 immediate packaging: 28 days if stored below 25ºC.
After first opening the immediate packaging store below 25ºC.
Do not open the aluminium foil before use of the LDPE vial.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

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

14. Marketing authorisation numbers and pack sizes

MA number: To be completed nationally

Packaging types:
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.

15. Date on which the package leaflet was last revised

2024-12-11

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

16. Contact details

Marketing authorisation holder:
To be completed nationally