

# FERRIBION 100 mg/ml solution for injection

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder  
and manufacturer:

Bioveta, a. s.  
Komenského 212  
683 23 Ivanovice na Hané  
Czech Republic

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT FERRIBION 100 mg/ml solution for injection

Dextraferranum

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Composition of 1 ml:

**Active substance:**

Dextraferranum 100 mg

**Excipients:**

Phenol 5.0 mg

Ferribion 100 mg/ml is a reddish brown, clear, slightly viscous solution for injection, non-transparent in a thicker layer.

## 4. INDICATION(S)

Primary anaemia, particularly hypochromic and aferric, in livestock with symptomatic depression, pallid mucosa, subnormal temperature and possible diarrhoea of uninfectious origin. Secondary anaemia due to the long-term haemorrhage caused by injuries, long-term surgical interventions and complicated deliveries; anaemia caused by the primary or secondary parasitic affections; supportive therapy at infectious diseases and states of debility.

## 5. CONTRAINDICATIONS

None.

## 6. ADVERSE REACTIONS

None.

## 7. TARGET SPECIES

Cattle, horses, sheep, goats, piglets, dogs, minks, foxes.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

|                           | Prophylactically | Therapeutically                                                                               |
|---------------------------|------------------|-----------------------------------------------------------------------------------------------|
| Adult cattle, horse       | 4 – 8 ml         | 8 – 12 ml                                                                                     |
| Calf, sheep, goat         | 2 – 4 ml         | 4 – 6 ml                                                                                      |
| Piglet (2 – 3 days old)   | 1 – 2 ml         | 2 – 2.5 ml                                                                                    |
| Lamb                      | 1.5 – 2.5 ml     | 2 – 4 ml                                                                                      |
| Dog                       | 1 – 2 ml         | Prophylactic doses<br>should be repeated<br>2 – 3 times<br>at the intervals<br>of 1 – 2 weeks |
| Mink (8 – 12 weeks old)   | 0.5 ml           |                                                                                               |
| Mink (3 months and above) | 1 ml             |                                                                                               |
| Fox (6 – 12 weeks old)    | 1 ml             |                                                                                               |
| Fox (3 months and above)  | 2 ml             |                                                                                               |

## 9. ADVICE ON CORRECT ADMINISTRATION

Intramuscularly, with a sufficiently thin needle so that the amount applied to one injection spot shall not exceed 5 ml.

The injection is applied into the gluteal musculature on a medial thigh surface and into the neck musculature in piglets and other animals, respectively.

## 10. WITHDRAWAL PERIOD

No withdrawal periods.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store below 25°C.

Protect from light.

Protect from frost.

Do not use after the expiry date stated on the package.

Shelf-life after first opening the container: 28 days.

## 12. SPECIAL WARNING(S)

Avoid contact with skin, eyes and mucous membranes.

After contact with skin or mucosa, wash immediately with plenty of water, take off all contaminated clothing which is in direct contact with skin. In case of contact with eyes, rinse with plenty of water. If irritation occurs, seek medical advice.

Parenterally administered iron preparations can cause allergic or anaphylactoid reaction.

In case of accidental ingestion or self-injection seek medical advice immediately and show the doctor the package leaflet or label.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2012