belfer®

100 mg/ml Solution for injection

for horses, cattle, pigs, sheep, goats and dogs

Active ingredient: Iron (III) as iron (III) hydroxide dextran complex

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta/ Germany

Name of the veterinary medicinal product
belfer 100 mg/ml
Solution for injection for horses, cattle, pigs, sheep, goats and dogs
Iron (III) as iron (III) hydroxide dextran complex

Statement of the active substance(s) and other ingredient(s)
Each ml contains:

Active substance:	
Iron (III) as iron (III) hydroxide dextran complex	100 mg
Excipients:	
Methyl-4-hydroxybenzoate sodium	1.05 mg
Propyl-4-hydroxybenzoate sodium	0.16 mg

Indications
For treatment of iron deficiency and iron deficiency anaemia.
For prophylaxis of iron deficiency anaemia in piglets.

Contraindications
Do not use in animals suffering from an infectious disease, especially diarrhoea.
Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Adverse reactions
In very rare cases injection of iron dextran may cause hypersensitivity or even anaphylactic reactions, which may be serious or fatal on individual occasions. In new-born piglets vitamin E and selenium deficiency is considered a particular risk factor.

Idiosyncratic sometimes fatal reactions occur in horses.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system.

Target species
Horse (suckling foals), cattle, pig, sheep, goat, dog

Dosage for each species, route(s) and method of administration
For intramuscular or subcutaneous use in piglets, pigs and calves.
For intramuscular use in foals, sheep, goats, cattle and dogs.

- Piglets:
  100 mg Iron III / kg b.w., equivalent to 1 ml belfer per kg body weight.
  For prophylaxis give a single injection between the 1. and 3. day of life.
  A second injection in the 3. week of life of the piglets is recommended.
- Calves, foals:
  10 - 30 mg Iron III / kg b.w., equivalent to 0.1 - 0.3 ml belfer per kg body weight.
- Pigs:
  2 mg Iron III / kg b.w., equivalent to 0.2 ml belfer per 10 kg body weight.
- Sheep, goats:
  2 mg Iron III / kg b.w., equivalent to 0.2 ml belfer per 10 kg body weight.
- Cattle:
  1 mg Iron III / kg b.w., equivalent to 1 ml belfer per 100 kg body weight.
- Dogs:
  1 - 2 mg Iron III / kg b.w., equivalent to 0.1 - 0.2 ml belfer per 10 kg body weight.
  Initial parenteral therapy in dogs should be followed by oral therapy.

For single administration.

If necessary, a second injection can be given 8 – 10 days following the first treatment.
Do not inject more than 10 ml **belfer** per injection site.
When treating groups of animals in one run, use a multiple dose syringe to avoid excess broaching of the stopper.

Advice on correct administration
Not applicable.

Withdrawal period
Horse, cattle, pig, sheep, goat:
Meat and offal zero days

Horse, cattle, sheep, goat:
Milk: zero days

Special storage precautions
Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Protect from light.
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: 14 days

Special warning(s)
Special warnings for each target species:
Iron deficiency anaemia in horses (foals) is very rare because iron availability in the normal diet is usually adequate and horses have an innate ability to conserve iron. However, iron deficiency may develop in young suckling foals and may be caused by limited storage of body iron, increased iron demand as a result of fast growth or low concentrations of iron in the mare's milk. While oral supplementation should be preferred in horses parenteral supplementation might be necessary in case of severely affected general condition, anorexia or impaired intestinal absorption. Particular effort and experience is required to diagnose iron deficiency in horses with appropriate diagnostic tests.

Special precautions for use in animals:
Do not inject more than 10 ml of the product per injection site.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to iron (III) hydroxide dextran complex or to any of the excipients should not administer the product.
Avoid contact with skin, mucous membranes and eyes.
Accidental spillage onto skin or into the eyes should be thoroughly rinsed off with water.
Wash hands after use.
In sensitive individuals iron dextran may cause anaphylactic reactions after injection.
Administration should be performed with caution in order to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy, Lactation or Lay:
Not applicable.

Interaction with other medicinal products and other forms of interaction:
The absorption of concomitantly administered oral iron may be reduced. See also section "Incompatibilities".

Overdose (symptoms, emergency procedures, antidotes):
Following overdose, gastro-intestinal disturbances, as well as cardiac and circulatory failure may occur.
Large amounts of iron administered by injection may result in iron overload of important immune cells which in turn may reduce immunological capability.

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

Special precautions for the disposal of unused product or waste materials, if any
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

Date of revision of the text
21.11.2017

Marketing authorisation number
402337.00.00 (Germany)

Other information
Pack size:
1 x 100 ml
6 x 100 ml
12 x 100 ml

Not all pack sizes may be marketed.

For animal treatment only.

To be supplied only on veterinary prescription.