SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

belfer 100 mg/ml (AT, CY, DE, EE, EL, ES, HU, LT, LV, PT, RO, SI)
belfer vet. 100 mg/ml (DK, FI; IS, SE)
BelaFer 100 mg/ml (PL)

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, dark red-brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For treatment of iron deficiency and iron deficiency anaemia.

For prophylaxis of iron deficiency anaemia in piglets.

4.3 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.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

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).

The occurrence of undesirable effects after application of iron (III) hydroxide dextran complex should be reported to the national health authorities or the marketing authorisation holder.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced. See also section 6.2.

4.9 Amounts to be administered and administration route

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 single injection between the 1st and 3rd day of life. A second injection in the 3rd 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.

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

Following overdose, gastro-intestinal disturbances, as well as cardiac and circulatory failure may occur.
Large amounts of iron administered by the parenteral route may result in transient reduced capacity of the immune system due to iron overload of lymph macrophages.

4.11 Withdrawal period(s)

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

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron, parenteral preparations
ATCvet code: QB03AC

5.1 Pharmacodynamic properties

Iron is an essential trace element for the organism. It is part of the haemoglobin and the myoglobin molecule, responsible for transport of oxygen. But also in some enzymes, e.g. cytochrome, catalases, and peroxidases, iron is an essential component.
Because of a high grade of recycling of iron in the metabolism and an almost sufficient intake with the feed, iron deficiency occurs rarely in adult animals.

5.2 Pharmacokinetic particulars

Following intramuscular injection the iron is absorbed within three days by the lymphatic tissue, whereby Fe^{3+} is released from the dextran complex and stored as ferritin in the deposit organs, mainly liver, spleen, and reticuloendothelial system. In the blood, free iron is bound to transferrin (transport form) and is mainly used for haemoglobin synthesis. Iron released in metabolism processes is recycled by 90%, therefore excretion is limited.
Following intramuscular or subcutaneous injection of belfer in the piglet, the physiological essential iron concentrations in plasma (plasma resp. serum values of ≥ 18 µmol iron/l) are obtained within 1-6 hours and are maintained for at least 48 hours. The half-life ranges between app. 30 and 50 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl-4-hydroxybenzoate sodium
Propyl-4-hydroxybenzoate sodium
Sodium edetate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf life of the medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 14 days

6.4. Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Protect from light.

6.5 Nature and composition of immediate packaging

100 ml amber glass vial with brombutyl rubber stoppers and aluminium caps.

Pack sizes:
1 x 100 ml
6 x 100 ml
12 x 100 ml

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

belfer 100 mg/ml (AT, CY, DE, EE, EL, ES, HU, LT, LV, PT, RO, SI)
belfer vet. 100 mg/ml (SE, IS, DK, FI)
BelaFer 100 mg/ml (PL)
Solution for injection for horses, cattle, pigs, sheep, goats and dogs
Iron (III) as iron (III) hydroxide dextran complex

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Iron (III) as iron (III) hydroxide dextran complex	100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
After first opening, use within 14 days.
Once opened, use by …

11. SPECIAL STORAGE CONDITIONS

Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard Box with 1, 6 or 12 vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

belfer 100 mg/ml
(AT, CY, DE, EE, EL, ES, HU, LT, LV, PT, RO, SI)
belfer vet. 100 mg/ml (SE, IS, DK, FI)
BelaFer 100 mg/ml (PL)

Solution for injection for horses, cattle, pigs, sheep, goats and dogs
Iron (III) as iron (III) hydroxide dextran complex.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Iron (III) as iron (III) hydroxide dextran complex	100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
6 x 100 ml
12 x 100 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 14 days

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder
Bela-Pharm GmbH & Co. KG
Lohner Straße 19
49377 Vechta
Germany

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

belfer 100 mg/ml (AT, CY, DE, EE, EL, ES, HU, LT, LV, PT, RO, SI)
belfer vet. 100 mg/ml (SE, IS, DK, FI)
BelaFer 100 mg/ml (PL)

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

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 responsible for batch release:
bela-pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

2. 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

3. 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

4. INDICATION(S)

For treatment of iron deficiency and iron deficiency anaemia.

For prophylaxis of iron deficiency anaemia in piglets.

5. 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.

6. 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.

7. TARGET SPECIES

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

8. 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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

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

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

11. 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

12. 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.

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.