[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucobel 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (AT, DE, IE, NL, RO, PT)

Glucobel vet. 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (FI, SE)

Belabel vet.
40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (DK, NO)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contains:

Active substance:
Glucose monohydrate 44.0 g
(equivalent to 40.0 g glucose, anhydrous)

Excipients:

Qualitative composition of excipients and other constituents
Water for injections

Solution for infusion.
Clear, colourless to slightly yellowish solution, free from visible particles.

Theoretical osmolarity	2220 mOsm/l
pH value	3.5 – 6.5
Caloric value	6698 kJ/l (1600 kcal/l)

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, sheep, goats, pigs, dogs and cats.

3.2 Indications for use for each target species

For infusion therapy in horse, cattle, sheep, goat, pig, dog and cat:
- to partially or completely cover the carbohydrate requirements,
- for acute hypoglycaemia,

For infusion therapy in cattle, sheep and goat:
- in metabolic syndromes with concomitant hypoglycaemia (ketosis).

3.3 Contraindications

Do not use in cases of:
Hyperglycaemia, hyperhydration, peripheral oedema, anuria, acidosis, electrolyte deficiency, hypotonic dehydration, intracranial or intraspinal bleeding, untreated diabetes mellitus, Addison's disease (hypoadrenocorticism).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Blood and urinary glucose levels, electrolyte and water balance should be monitored regularly.
At high doses, potassium and phosphate should be substituted as required.
Due to its osmotic effect, hypertonic carbohydrate solutions increase the intravasal volume. Especially in case of cardiovascular diseases this could lead to hypertonia, hyperhydration and oedema and even cause hyperosmolaric coma. Thus in animals with cardio-vascular or renal disease, use only according to the benefit-risk assessment by the responsible veterinarian. In those animals the veterinary medicinal product must be administered very slowly and the animal must be closely monitored for signs of hyperhydration such as tachypnoea and respiratory distress.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product should be handled according to the established rules for the use of injection/infusion solutions and strict precautions should be taken 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.

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

3.6 Adverse events

Horses, cattle, sheep, goats, pigs, dogs and cats

Undetermined frequency (Frequency cannot be estimated from the available data):	Hypervolaemia Electrolyte disorder (Hypokalaemia, Hypomagnesemia, Hypophosphataemia), Hyperglycaemia Glucosuria Thrombophlebitis at the injection site[1,2]

[1] In case of rapid intravenous administration of hypertonic (30% to 50%) solutions in emergency cases.

[2] Inadequate infusion technique may cause extravasation, infection at the injection site, local pain, vein irritation or phlebitis, which may extend from the injection site, or even thrombosis.
If adverse reactions occur, the infusion must be stopped immediately.

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

No laboratory studies have been performed with the veterinary medicinal product. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Interactions with certain antibiotics (e.g. beta-lactam antibiotics, tetracyclines, sulfadiazine sodium) and heparin are known.
This veterinary medicinal product is incompatible with calcium disodium EDTA, histamine diphosphate, warfarin sodium and thiopental sodium.
Glucose solutions should not be administered simultaneously with, before or after the administration of blood through the same infusion equipment, as this may lead to pseudo-agglutination.

3.9 Administration routes and dosage

Intravenous use.

Administer slowly by intravenous infusion, not exceeding an infusion rate of 0.5 ml/kg body weight/h. The dose should be determined according to the body weight of the animal and the desired energy supply and divided into several infusions per day.

Dosage:
Cattle and horse:
200 - 400 g glucose (corresponding to 500 - 1000 ml of the veterinary medicinal product/animal) every 24 hours.

Sheep, goat and pig:
50 - 100 g glucose (corresponding to 125 - 250 ml of the veterinary medicinal product/animal) every 24 hours.
Hypoglycaemia in piglets:
0.75 g glucose (corresponding to 1.87 ml of the veterinary medicinal product/animal) every 4 - 6 hours.

Dog and cat:
5 - 25 g glucose (corresponding to 12.5 - 62.5 ml of the veterinary medicinal product/animal) every 24 hours.

Advice on correct administration:
- Do not administer subcutaneously.
- Fluids for intravenous use should be warmed up to body temperature before administration.
- Aseptic conditions must be maintained during administration.
- For single use only.
- Use only if the solution is clear and free of visible particles and the container is undamaged.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosage of fluids can lead to hyperhydration, hypertonia and extravascular edema. A possible clinical sign is respiratory distress. In this case infusion should be minimized or stopped and if needed oxygen therapy and diuretics should be administered. Excessive administration of glucose can lead to hyperglycemia, glucosuria and polyuria.
Transient hyperglycemia can be avoided by continuous intravenous drip or in non-food-producing animals by simultaneous application of insulin.

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

Cattle, sheep, goat and horse:
Meat and offal: zero days
Milk: zero hours

Pig:
Meat and offal: zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BA03

4.2 Pharmacodynamics

Glucose is a physiological energy carrier that can be metabolised by almost all of the body cells. Via glycolysis, glucose is degraded to pyruvate or lactate that are introduced into the citric acid cycle and pentose-phosphate cycle and deliver energy as adenosine-tri-phosphate.
Hypertonic glucose solutions are used for the treatment of metabolic disorders with concomitant hypoglycaemia, such as ketosis, as glucose reduces the catabolism of lipids, thus reducing the formation of ketone bodies.

4.3 Pharmacokinetics

The intravenous infusion ensures rapid distribution. The constituents of the infusion solution are metabolised and excreted via the same metabolic pathways as water and glucose from regular dietary sources.
Excess glucose is excreted via the kidneys. At normal blood concentrations, it is filtered through the renal tubules but it is almost completely reabsorbed, so that its concentration in urine drops almost to zero.
Due to its osmotically active diuretic properties, glucose increases the volume of water present in urine.

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: Use immediately.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

500 ml and 750 ml polypropylene bottles with bromobutyl stopper and aluminium cap.

Package sizes: 1 x 500 ml, 12 x 500 ml, 1 x 750 ml, 12 x 750 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. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co.KG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. (AT, DE, DK, FI, IE, SE)
Veterinary medicinal product not subject to prescription. (NL, NO, RO, PT)

Detailed information on this veterinary medicinal product is available in the Union Product Database.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
The applicant does not intend to have a separate template and reduced texts for the immediate label.

{12 x 500 ml; 12 x 750 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucobel 40 g/100 ml solution for infusion (AT, DE, IE, NL, RO, PT)

Glucobel vet. 40 g/100 ml solution for infusion (FI, SE)

Belabel vet.
40 g/100 ml solution for infusion (DK, NO)

2. STATEMENT OF ACTIVE SUBSTANCES

100 ml contains:

Active substance:
Glucose monohydrate 44.0 g
(equivalent to 40.0 g glucose, anhydrous)

3. PACKAGE SIZE

12 x 500 ml
12 x 750 ml

4. TARGET SPECIES

Horses, cattle, sheep, goats, pigs, dogs and cats.

5. INDICATIONS

Not applicable in case of products subject to veterinary prescription.

6. ROUTES OF ADMINISTRATION

Intravenous use.
Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle, sheep, goat and horse:
Meat and offal: zero days
Milk: zero hours

Pig:
Meat and offal: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately. Dispose of any unused product.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co.KG

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{500 ml, 750 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucobel 40 g/100 ml solution for infusion (AT, DE, IE, NL, RO, PT)

Glucobel vet. 40 g/100 ml solution for infusion (FI, SE)

Belabel vet.
40 g/100 ml solution for infusion (DK, NO)

2. STATEMENT OF ACTIVE SUBSTANCES

100 ml contains:

Active substance:
Glucose monohydrate 44.0 g
(equivalent to 40.0 g glucose, anhydrous)

3. TARGET SPECIES

Horses, cattle, sheep, goats, pigs, dogs and cats.

4. ROUTES OF ADMINISTRATION

Intravenous use.
Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle, sheep, goat and horse:
Meat and offal: zero days
Milk: zero hours

Pig:
Meat and offal: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately. Dispose of any unused product.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Bela-Pharm GmbH & Co.KG

9. BATCH NUMBER

Lot {number}

Additional Information, based on Article 13 Regulation (EU) 2019/6:

PACKAGE SIZE

500 ml
750 ml

THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

MARKETING AUTHORISATION NUMBERS

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Glucobel 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (AT, DE, IE, NL, RO, PT)

Glucobel vet. 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (FI, SE)

Belabel vet.
40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (DK, NO)

2. Composition

100 ml contains:

Active substance:
Glucose monohydrate 44.0 g
(equivalent to 40.0 g glucose, anhydrous)

Clear, colourless to slightly yellowish solution, free from visible particles.

Theoretical osmolarity	2220 mOsm/l
pH value	3.5 – 6.5
Caloric value	6698 kJ/l (1600 kcal/l)

3. Target species

Horses, cattle, sheep, goats, pigs, dogs and cats.

4. Indications for use

For infusion therapy in horse, cattle, sheep, goat, pig, dog and cat:
- to partially or completely cover the carbohydrate requirements,
- for acute hypoglycaemia,

For infusion therapy in cattle, sheep and goat:
- in metabolic syndromes with concomitant hypoglycaemia (ketosis).

5. Contraindications

Do not use in cases of:
Hyperglycaemia, hyperhydration, peripheral oedema, anuria, acidosis, electrolyte deficiency, hypotonic dehydration, intracranial or intraspinal bleeding, untreated diabetes mellitus, Addison's disease (hypoadrenocorticism).

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Blood and urinary glucose levels, electrolyte and water balance should be monitored regularly.
At high doses, potassium and phosphate should be substituted as required.

Due to its osmotic effect, hypertonic carbohydrate solutions increase the intravasal volume. Especially in case of cardiovascular diseases this could lead to hypertonia, hyperhydration and oedema and even cause hyperosmolaric coma. Thus in animals with cardio-vascular or renal disease, use only according to the benefit-risk assessment by the responsible veterinarian. In those animals the veterinary medicinal product must be administered very slowly and the animal must be closely monitored for signs of hyperhydration such as tachypnoea and respiratory distress.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product should be handled according to the established rules for the use of injection/infusion solutions and strict precautions should be taken 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 and lactation:
No laboratory studies have been performed with the veterinary medicinal product. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Interactions with certain antibiotics (e.g. beta-lactam antibiotics, tetracyclines, sulfadiazine sodium) and heparin are known.
This veterinary medicinal product is incompatible with calcium disodium EDTA, histamine diphosphate, warfarin sodium and thiopental sodium.
Glucose solutions should not be administered simultaneously with, before or after the administration of blood through the same infusion equipment, as this may lead to pseudo-agglutination.

Overdose:
Overdosage of fluids can lead to hyperhydration, hypertonia and extravascular edema. A possible clinical sign is respiratory distress. In this case infusion should be minimized or stopped and if needed oxygen therapy and diuretics should be administered. Excessive administration of glucose can lead to hyperglycemia, glucosuria and polyuria.
Transient hyperglycemia can be avoided by continuous intravenous drip or in non-food-producing animals by simultaneous application of insulin.

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

7. Adverse events

Horses, cattle, sheep, goats, pigs, dogs and cats

Undetermined frequency (Frequency cannot be estimated from the available data):	Hypervolaemia Electrolyte disorder (Hypokalaemia, Hypomagnesemia, Hypophosphataemia), Hyperglycaemia Glucosuria Thrombophlebitis at the injection site[1,2]

[1] In case of rapid intravenous administration of hypertonic (30% to 50%) solutions in emergency cases.

[2] Inadequate infusion technique may cause extravasation, infection at the injection site, local pain, vein irritation or phlebitis, which may extend from the injection site, or even thrombosis.
If adverse reactions occur, the infusion must be stopped immediately.

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.

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

Intravenous use.

Administer slowly by intravenous infusion, not exceeding an infusion rate of 0.5 ml/kg body weight/h. The dose should be determined according to the body weight (b.w.) of the animal and the desired energy supply and divided into several infusions per day.

Dosage:
Cattle and horse:
200 - 400 g glucose (corresponding to 500 - 1000 ml of the veterinary medicinal product/animal) every 24 hours.

Sheep, goat and pig:
50 - 100 g glucose (corresponding to 125 - 250 ml of the veterinary medicinal product/animal) every 24 hours.
Hypoglycaemia in piglets:
0.75 g glucose (corresponding to 1.87 ml of the veterinary medicinal product/animal) every 4 - 6 hours.

Dog and cat:
5 - 25 g glucose (corresponding to 12.5 - 62.5 ml of the veterinary medicinal product/animal) every 24 hours.

9. Advice on correct administration

- Do not administer subcutaneously.
- Fluids for intravenous use should be warmed up to body temperature before administration.
- Aseptic conditions must be maintained during administration.
- For single use only.
- Use only if the solution is clear and free of visible particles and the container is undamaged.

10. Withdrawal periods

Cattle, sheep, goat and horse:
Meat and offal: zero days
Milk: zero hours

Pig:
Meat and offal: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Shelf life after first opening the container: Use immediately.

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 national collection systems applicable to the veterinary medicinal product concerned.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. (AT, DE, DK, FI, IE, SE)
Veterinary medicinal product not subject to prescription. (NL, NO, RO, PT)

14. Marketing authorisation numbers and pack sizes

1 x 500 ml, 12 x 500 ml, 1 x 750 ml, 12 x 750 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

[To be completed nationally]

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

{Combined Label on 500 ml and 750 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucobel 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (AT, DE, IE, NL, RO, PT)

Glucobel vet. 40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (FI, SE)

Belabel vet.
40 g/100 ml solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (DK, NO)

2. COMPOSITION

100 ml contains:
Active substance:
Glucose monohydrate 44.0 g
(equivalent to 40.0 g glucose, anhydrous)

Clear, colourless to slightly yellowish solution, free from visible particles.

Theoretical osmolarity	2220 mOsm/l
pH value	3.5 – 6.5
Caloric value	6698 kJ/l (1600 kcal/l)

3. PACKAGE SIZE

500 ml
750 ml

4. TARGET SPECIES

Horses, cattle, sheep, goats, pigs, dogs and cats.

5. INDICATIONS FOR USE

Indications for use
For infusion therapy in horse, cattle, sheep, goat, pig, dog and cat:
- to partially or completely cover the carbohydrate requirements,
- for acute hypoglycaemia,

For infusion therapy in cattle, sheep and goat:
- in metabolic syndromes with concomitant hypoglycaemia (ketosis).

6. CONTRAINDICATIONS

Contraindications
Do not use in case of:
Hyperglycaemia, hyperhydration, peripheral oedema, anuria, acidosis, electrolyte deficiency, hypotonic dehydration, intracranial or intraspinal bleeding, untreated diabetes mellitus, Addison's disease (hypoadrenocorticism).

7. SPECIALS WARNING(S)

Special warnings

Special precautions for safe use in the target species:
Blood and urinary glucose levels, electrolyte and water balance should be monitored regularly.
At high doses, potassium and phosphate should be substituted as required.
Due to its osmotic effect, hypertonic carbohydrate solutions increase the intravasal volume. Especially in case of cardiovascular diseases this could lead to hypertonia, hyperhydration and oedema and even cause hyperosmolaric coma. Thus in animals with cardio-vascular or renal disease, use only according to the benefit-risk assessment by the responsible veterinarian. In those animals the veterinary medicinal product must be administered very slowly and the animal must be closely monitored for signs of hyperhydration such as tachypnoea and respiratory distress.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The product should be handled according to the established rules for the use of injection/infusion solutions and strict precautions should be taken 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 and lactation:
No laboratory studies have been performed with the veterinary medicinal product. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Interactions with certain antibiotics (e.g. beta-lactam antibiotics, tetracyclines, sulfadiazine sodium) and heparin are known.
This veterinary medicinal product is incompatible with calcium disodium EDTA, histamine diphosphate, warfarin sodium and thiopental sodium.
Glucose solutions should not be administered simultaneously with, before or after the administration of blood through the same infusion equipment, as this may lead to pseudo-agglutination.

Overdose:
Overdosage of fluids can lead to hyperhydration, hypertonia and extravascular edema. A possible clinical sign is respiratory distress. In this case infusion should be minimized or stopped and if needed oxygen therapy and diuretics should be administered. Excessive administration of glucose can lead to hyperglycemia, glucosuria and polyuria.
Transient hyperglycemia can be avoided by continuous intravenous drip or in non-food-producing animals by simultaneous application of insulin.

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

8. ADVERSE EVENTS

Adverse events

Horses, cattle, sheep, goats, pigs, dogs and cats

Undetermined frequency (Frequency cannot be estimated from the available data):	Hypervolaemia Electrolyte disorder (Hypokalaemia, Hypomagnesemia, Hypophosphataemia), Hyperglycaemia Glucosuria Thrombophlebitis at the injection site[1,2]

[1] In case of rapid intravenous administration of hypertonic (30% to 50%) solutions in emergency cases.

[2] Inadequate infusion technique may cause extravasation, infection at the injection site, local pain, vein irritation or phlebitis, which may extend from the injection site, or even thrombosis.
If adverse reactions occur, the infusion must be stopped immediately.

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 orthe local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Intravenous use.

Administer slowly by intravenous infusion, not exceeding an infusion rate of 0.5 ml/kg body weight/h. The dose should be determined according to the body weight of the animal and the desired energy supply and divided into several infusions per day.

Dosage:
Cattle and horse:
200 - 400 g glucose (corresponding to 500 - 1000 ml of the veterinary medicinal product/animal) every 24 hours.

Sheep, goat and pig:
50 - 100 g glucose (corresponding to 125 - 250 ml of the veterinary medicinal product/animal) every 24 hours.
Hypoglycaemia in piglets:
0.75 g glucose (corresponding to 1.87 ml of the veterinary medicinal product/animal) every 4 - 6 hours.

Dog and cat:

5 - 25 g glucose (corresponding to 12.5 - 62.5 ml of the veterinary medicinal product/animal) every 24 hours.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

- Do not administer subcutaneously.
- Fluids for intravenous use should be warmed up to body temperature before administration.
- Aseptic conditions must be maintained during administration.
- For single use only.
- Use only if the solution is clear and free of visible particles and the container is undamaged.

11. WITHDRAWAL PERIODS

Withdrawal periods

Cattle, sheep, goat and horse:
Meat and offal: zero days
Milk: zero hours

Pig:
Meat and offal: zero days

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Shelf life after first opening the container: Use immediately.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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 national collection systems applicable to the veterinary medicinal product concerned.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. (AT, DE, DK, FI, IE, SE)
Veterinary medicinal product not subject to prescription. (NL, NO, RO, PT)

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

[MA-No.: *To be completed nationally*]

Pack sizes

1 x 500 ml, 12 x 500 ml, 1 x 750 ml, 12 x 750 ml.
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Bela-Pharm GmbH & Co.KG
Lohner Str. 19
49377 Vechta
Germany

Local representatives and contact details to report suspected adverse reactions:

[To be completed nationally]

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

EXP {mm/yyyy}
Once opened use immediately. Dispose of any unused product.

21. BATCH NUMBER

Lot{number}