[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucose Bernburg 400 mg/ml solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains

Active substance:
Glucose anhydrous 400 mg
(equivalent to glucose monohydrate 440 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hydrochloric acid, concentrated (for pH adjustment)	/
Sodium hydroxide (for pH adjustment)	/
Water for injections	/

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

Caloric value	1600 kcal/l
Titration acidity (to pH 7.4)	< 1.0 mmol/l
pH value	3.0 - 5.5

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, sheep, goats, pigs, dogs and cats

3.2 Indications for use, specifying the target species

Cattle, sheep and goat:
- Metabolic syndromes that occur with hypoglycaemia (ketosis, transport tetany).
- Increased energy demands in: sepsis, endotoxemia, trauma.

Pig:
- Increased energy demands in: sepsis, endotoxemia, trauma.
- Hypoglycaemia.

Horse, dog and cat:
- Increased energy demands in: sepsis, endotoxemia, trauma.

Generally, it is used for energy supply in all target animal species.

3.3 Contraindications

Do not use in case of:

- Intracranial or intraspinal bleeding.
- Untreated diabetes mellitus.
- Hypotonic dehydration.
- Depletion in electrolytes.
- Anuria.
- Peripheral oedemas.
- Addison's disease (hypoadrenocorticism) in small animals.
- Haemoperfusions.

3.4 Special warnings

None.

3.5 Special precautions for use

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is a hypertonic solution. Handle according to the established rules for the use of injectables and take extreme precautions 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.

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

3.6 Adverse events

Cattle, horses, sheep, goats, pigs, dogs and cats:

Undetermined frequency:	- Hyperglycaemia - Glucosuria - Electrolyte imbalances (hypokalaemia, hypomagnesaemia or hypophosphataemia) - Hypervolaemia - Phlebitis and/or clotting at the injection site[1] - Extravasation[2, 3] - Infection at the injection site[2, 3] - Local pain[2, 3] - Vein irritation or phlebitis[2, 3] - Thrombosis[2]

[1] may be caused by rapid intravenous administration of hypertonic solution (30-50%) in emergency cases

[2] may be caused by incorrect infusion technique

[3] may extend from the injection site

If adverse reactions occur, the infusion must be stopped.

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, 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Incompatibilities with certain antibiotics (e.g. beta-lactam antibiotics, tetracyclines, sulfadiazine sodium) and heparin are recognised.

3.9 Administration routes and dosage

Intravenous use

Administer slowly by intravenous infusion, thereby not exceeding an infusion rate of 0.5 ml/kg bodyweight /h.

- Cattle and horse: 200-400 g of glucose (equivalent to 500-1000 ml of veterinary medicinal product /animal) every 24 h.
- Sheep, goat and pig: 50-100 g of glucose (equivalent to 125-250 ml of veterinary medicinal product /animal), every 24 h.
  Hypoglycemia of piglets: 0.75 g of glucose (equivalent to 1.87 ml of veterinary medicinal product /animal), every 4-6 h.
- Dog and cat: 5-25 g of glucose (equivalent to 12.5-62.5 ml of veterinary medicinal product /animal), every 24 h.

Doses are administered according to the animal weight and the desired energy supply, being divided into several daily infusions.

Instructions for correct administration:
- Maintain aseptic precautions throughout administration.
- Do not administer via subcutaneous route.
- IV fluids should be warmed up to body temperature prior to administration.
- For single use only.
- Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

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

The administration of excess glucose can lead to hyperglycaemia, glycosuria and polyuria.

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, horses, sheep and goats:
Meat and offal: Zero days
Milk: Zero hours

Pigs:
Meat and offal: Zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BA03.

4.2 Pharmacodynamic

Glucose is one of the most common constituents of oral and parenteral fluids, including parenteral nutrition.
Hypertonic solutions are frequently administered in the treatment of metabolic diseases that are accompanied by hypoglycaemia, such as ketosis and transport tetany, thus preventing ketone bodies from accumulating.
Treatment with a 40 % glucose solution has a beneficial effect in animals suffering from sepsis, endotoxemia, trauma. This positive effect is based on supplementing glucose to meet the increased energy requirements in these conditions.

4.3 Pharmacokinetic

Intravenous infusion ensures rapid distribution. The constituent of the infusion solution is metabolised and excreted through the same pathways as water and glucose derived from normal dietary sources. Excess glucose is eliminated via the kidneys. When the blood concentration is normal, it is filtered through the renal tubules, but it is almost completely reabsorbed, such that its concentration in urine falls almost to zero.
Glucose, due to its osmotically active diuretic properties, increases the volume of water present in urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

The medicinal product is incompatible with calcium-disodium edetate, histamine diphosphate, sodium warfarin and sodium thiopental.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Glucose solutions should not be administered through the same infusion equipment simultaneously with, before, or after administration of blood, because of the possibility of pseudo-agglutination.

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.
Dispose of any unused product.

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

Polypropylene bottles with chlorobutyl rubber stopper and bordered aluminium/polypropylene flip cap.

1 bottle of 500 ml

10 bottles of 500 ml in cardboard box

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Serumwerk Bernburg AG

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

07/2022

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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