

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucose 40 g/100 ml B. Braun Vet Care solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

GlucosaVet 40 g/100 ml solución para perfusión para bovino, caballos, ovino, caprino, porcino, perros y gatos (ES)

Glucose B. Braun Vet Care 40 g/100 ml Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Schweine, Hunde und Katzen (AT, DE)

Glucose 40 g/100 ml B. Braun Vet Care solution pour perfusion pour bovins, chevaux, moutons, chèvres, porcins, chiens et chats (BE)

Glucose 40 g/100 ml B. Braun Vet Care oplossing voor infusie voor runderen, paarden, schapen, geiten, varkens, honden en katten (NL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contains:

Active substance:

Glucose monohydrate 44.0 g
(equivalent to anhydrous glucose 40.0 g)

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

Clear, colourless or almost colourless aqueous solution, free from visible particles

Caloric value	1600 kcal/l
Theoretical osmolarity	2220 mOsm/l
Titration acidity (to pH 7.4)	< 1.0 mmol/l
pH value	3.5 - 5.5

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, sheep, goat, pig, dog and cat

4.2 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.

4.3 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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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

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.

4.6 Adverse reactions (frequency and seriousness)

The rapid intravenous administration of hypertonic solutions (30 to 50%) (in emergency cases) may cause phlebitis and/or clotting at the injection site.

The infusion may cause:

- Hyperglycaemia and glycosuria
- Electrolyte imbalances (hypokalaemia, hypomagnesaemia or hypophosphataemia)
- Water imbalances (hypervolaemia)

Incorrect infusion technique may cause extravasation, infection at the injection site, local pain, vein irritation or phlebitis that may extend from the injection site, and even thrombosis.

If adverse reactions occur, the infusion must be stopped.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amounts to be administered and administration route

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.

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

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

4.11 Withdrawal period(s)

Cattle, horse, sheep, goat and pig:

Meat: Zero days

Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: blood substitutes and perfusion solutions - solutions for parenteral nutrition.

ATCvet code: QB05BA03

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICALS PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment)
Water for injections

6.2 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.

6.3 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 after opening the bottle.
Dispose of any unused product.

6.4 Special precautions for storage

Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottles of 500 and 1000 ml of capacity.

The additional closure cap on top of the sealed polyethylene container is made from high density polyethylene. Between the container and the closure cap an elastomeric latex free disk is placed.

Pack sizes:

Box containing 10 bottles of 500 ml

Box containing 10 bottles of 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

B. Braun Melsungen AG

Carl-Braun Straße 1

34212 Melsungen

Germany

Postal address:

34209 Melsungen

Germany

In Spain:

B. Braun VetCare SA

Ctra. de Terrassa, 121

08191 Rubí (Barcelona), Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

To be completed nationally

PROHIBITION OF SALE, SUPPLY AND/OR USE

Prescription conditions: **To be supplied only on veterinary prescription.**

Administration conditions: **To be administered only by a veterinary surgeon.**