

PACKAGE LEAFLET

Glucose 5 g/100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

B. Braun Melsungen AG

Carl-Braun Straße 1

34212 Melsungen

Germany

In Spain:

B. Braun VetCare SA

Ctra. de Terrassa, 121

08191 Rubí. (Barcelona), Spain

Postal address:

34209 Melsungen

Germany

Manufacturer responsible for batch release:

B. Braun Medical SA

Carretera de Terrassa, 121

08191 Rubí (Barcelona), Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Glucose 5 g/ 100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats

GlucosaVet 5g/100 ml solución para perfusión para bovino, caballos, ovino, caprino, porcino, perros y gatos

Glucosa (como monohidrato) (Spain)

Glucose B. Braun Vet Care 5 g/100 ml Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Schweine, Hunde und Katzen (Austria, Germany)

Glucose 5 g/100 ml B. Braun Vet Care solution pour perfusion pour bovins, chevaux, ovins, caprins, porcins, chiens et chats (Belgium)

Glucose 5 g/100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats (United Kingdom/Ireland)

Glucosio 5 g/100 ml B. Braun Vet Care soluzione per infusione per bovini, cavalli, pecore, capre, suini, cani e gatti (Italy)

Glucose 5 g/100 ml B. Braun Vet Care oplossing voor infusievoor runderen, paarden, schapen, geiten, varkens, honden en katten (Netherlands)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

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

100 ml contains:

Active substance:

Glucose monohydrate 5.5 g

(equivalent to anhydrous glucose 5.0 g)

Excipient:

Water for injections

Caloric value	837 kJ/l = 200 kcal/l
Theoretical osmolarity	278 mOsm/l
pH value	3.5 - 5.5

4. INDICATION(S)

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

- Treatment of dehydration (in the absence of shock)
- Parenteral rehydration
- Correction of hypernatremia
- Correction of hyperkalaemia
- Transient supportive treatment of hypoglycaemia

5. CONTRAINDICATIONS

Do not administer to hyperglycaemic animals.

This product is unsuitable for the correction of hypotonic dehydration. Do not use in animals with pre-existing peripheral oedema caused by a reduction in intravascular oncotic pressure.

This product is not suitable as a sole source of calorie requirements or as a substitute for oral or parenteral nutrition.

6. ADVERSE REACTIONS

In very rare cases administration of products by intravenous infusion may increase the risk of thrombosis.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals treated displaying adverse reaction(s)).
- 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.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intravenous use. Administer slowly via intravenous infusion.

This product should not be administered at a rate in excess of 10 ml/kg bodyweight/hour, otherwise glycosuria and osmotic diuresis may result.

Infusion rates should be calculated according to the presenting condition, bodyweight and degree of dehydration of the animal being treated. The total fluid volume to be administered should consider existing deficits, maintenance requirements and ongoing losses.

IV fluids should be warmed up to body temperature prior to administration.

Maintain aseptic precautions throughout administration.

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

9. ADVICE ON CORRECT ADMINISTRATION

For single use only.

10. WITHDRAWAL PERIOD(S)

Meat and offal: Zero days

Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

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

Use immediately after opening the bottle. Discard any unused product.

12. SPECIAL WARNING(S)

Special precautions for use in animals

This product does not contain electrolytes. Care should be taken to closely monitor electrolyte and phosphate balance in patients undergoing infusion of this product, and to adjust treatment accordingly. This product should be used with particular caution in patients with the following conditions:

Diabetes mellitus

Intracranial or intraspinal bleeding

Anuria

Addisons disease

Severe or long standing hypernatraemia should be corrected gradually.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None

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

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

Overdose (symptoms, emergency procedures, antidotes)

Overperfusion can lead to overhydration, hypertension and extravascular fluid accumulation. Symptoms may include respiratory distress. In the case of overperfusion, reduce or cease fluid infusion and administer oxygen, diuretics and adjunctive treatment as necessary. Monitor respiration and heart rate, fluid output, electrolyte balance and blood glucose during administration.

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

Incompatibilities

The medicinal product is incompatible with calcium-disodium edetate, histamine diphosphate, sodium warfarin and sodium thiopental.

The mixture with other medicinal products may cause incompatibilities. Checking the compatibility of any mixture is the responsibility of the user.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon 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

Nature and composition of immediate packaging:

Polyethylene low density bottles of 100, 250, 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:

Bottle of 100 ml

Bottle of 250 ml

Bottle of 500 ml

Bottle of 1000 ml

1 cardboard box containing 20 bottles of 100 ml

1 cardboard box containing 20 bottles of 250 ml

1 cardboard box containing 10 bottles of 500 ml

1 cardboard box containing 10 bottles of 1000 ml

Not all pack sizes may be marketed.

For animal treatment only.

To be supplied only on veterinary prescription.

In Spain only: To be administered only by a veterinary surgeon.