

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

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

Marketing authorization 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

Manufacturer responsible for batch release

B. Braun Medical SA
Ctra. de Terrassa, 121
08191 Rubí (Barcelona), Spain

2. 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)

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

100 ml contains:

Active substance:

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

Excipients, qs

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

4. INDICATION(S)

- 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.

5. 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.

6. ADVERSE REACTIONS

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.

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

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

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.

9. ADVICE ON 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.

10. WITHDRAWAL PERIOD(S)

Cattle, horse, sheep, goat and pig:

Meat: 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 which is stated on the label after EXP. The expiry dates refers to the last day of that month.

Shelf life after first opening the container: Use immediately after opening the bottle. Dispose of any unused product.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None

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.

Pregnancy and lactation:

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.

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):

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.

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.

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

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

To be completed nationally

15. OTHER INFORMATION

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.

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

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