

LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardbox labels with low density polyethylene bottles

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

In Spain: GlucosaVet 40 g/100 ml solución para perfusión para bovino, equino, ovino, caprino, porcino, perros y gatos

Glucosa (como monohidrato)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 ml contains:

Active substance:

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

Excipients:

Hydrochloric acid (to adjust pH)

Water for injections

3. PHARMACEUTICAL FORM

Solution for infusion

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

4. PACKAGE SIZE

10 x 500 ml

10 x 1000 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle, horse, sheep, goat and pig

Meat: zero days.

Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Use immediately after opening the bottle. Dispose of any unused product.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

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

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
34209 Melsungen,
Germany

In Spain:
B. Braun VetCare SA,
08191 Rubí (Barcelona), Spain

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER'S BATCH NUMBER**

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Labels, low density polyethylene bottles

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

In Spain: GlucosaVet 40 g/100 ml solución para perfusión para bovino, equino, ovino, caprino, porcino, perros y gatos
Glucosa (como monohidrato)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 ml contains:

Active substance:

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

Excipients:

Hydrochloric acid (to adjust pH)
Water for injections

3. PHARMACEUTICAL FORM

Solution for infusion

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

4. PACKAGE SIZE

500 ml
1000 ml

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle, horse, sheep, goat and pig

Meat: zero days.

Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Use immediately after opening the bottle. Dispose of any unused product.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

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

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
34209 Melsungen
Germany

In Spain:
B. Braun VetCare SA,
08191 Rubí (Barcelona), Spain

16. MARKETING AUTHORISATION NUMBER(S)

| |
|--|
| 17. MANUFACTURER'S BATCH NUMBER |
|--|

Lot

PACKAGE LEAFLET

**PACKAGE LEAFLET FOR
GLUCOSAVET 40 g/100 ml SOLUCION PARA PERFUSION
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

GLUCOSAVET 40 g/100 ml SOLUCION PARA PERFUSION for cattle, horse, sheep, goat, pig, dog and cat.

Glucose monohydrate.

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

100 ml contains:

Active substance:

Glucose monohydrate 44.0 g

(equivalent to anhydrous glucose 40.0 g)

Excipients:

Hydrochloric acid (to adjust pH)

Water for injection, to

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).
- Pathological states that occur with hypovolaemia: septic, endotoxic, traumatic or surgical shock.

• Pig:

- Pathological states that occur with hypovolaemia: septic, endotoxic, traumatic or surgical shock.
- Hypoglycaemia.
- Horse, dog and cat:
 - Pathological states that occur with hypovolaemia: septic, endotoxic, traumatic or surgical shock.

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.
- 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 or 540%) (in emergency cases) may cause phlebitis and/or clotting at the injection site.

The infusion may cause:

- Hyperglycaemia.
- 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 serious effects or other effects not mentioned in this package leaflet, 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 b.w./h.

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

- 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

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.

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

12. SPECIAL WARNING(S)

Special precautions for use in animals

Blood 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

None known.

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.

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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 low density polyethylene bottles of 500 ml

Box containing 10 low density polyethylene bottles of 1000 ml

Not all pack sizes may be marketed.

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To be administered only by a veterinary surgeon.