# LABELLING

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polyethylene bottles of 100, 250, 500 and 1000 ml

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion

## 2. STATEMENT OF ACTIVE SUBSTANCES

**Each of 100 ml contains:**

*Active substance:*
Sodium chloride 0.9 g

## 3. PACKAGE SIZE

20x100 ml
20x250 ml
10x500 ml
10x1000 ml

## 4. TARGET SPECIES

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

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Intravenous use and external use for wound irrigation and moistening of compresses.

## 7. WITHDRAWAL PERIODS

Withdrawal period: zero days

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use immediately. Dispose of any unused product.

## 9. SPECIAL STORAGE PRECAUTIONS

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

## 13. NAME OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

## 14. MARKETING AUTHORISATION NUMBERS

Vm 03551/3000

## 15. BATCH NUMBER

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

Polyethylene bottles of 100, 250, 500 and 1000 ml

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion

## 2. STATEMENT OF ACTIVE SUBSTANCES

**Each of 100 ml contains:**

*Active substance:*
Sodium chloride 0.9 g

## 3. TARGET SPECIES

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

## 4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use and external use for wound irrigation and moistening of compresses.

## 5. WITHDRAWAL PERIODS

Withdrawal period: zero days

## 6. EXPIRY DATE

EXP. {mm/yyyy}
Once opened use immediately. Dispose of any unused product.

## 7. SPECIAL STORAGE CONDITIONS

## 8. NAME OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

## 9. BATCH NUMBER

Lot {number}

# PACKAGE LEAFLET

# PACKAGE LEAFLET:

## 1. Name of the veterinary medicinal product

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats.

## 2. Composition

Each of 100 ml contains:

Sodium chloride 0.9 g
Water for injection

Clear and colourless solution, free from particles.

## 3. Target species

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

## 4. Indications for use

It is used in all the animal target species for:

- States of dehydration and hypovolaemia
- Deficiency of sodium (hyponatraemia) and chloride (hypochloraemia)
- Hypochloraemic alkalosis management
- Vehicle solution for compatible drugs
- External use for wound irrigation and moistening of compresses

## 5. Contraindications

Do not use in animals with:
- Hypertonic dehydration
- Hypernatraemia
- Hyperchloraemia
- Hyperhydration
- Acidosis
- Syndrome of oedema and ascites
- In cases when sodium restriction is indicated

## 6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
Use with caution in animals with cardiac or renal impairment as sodium overload may occur. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

Use with caution post surgery/trauma as sodium excretion may be impaired. Use with caution in animals with hypokalaemia. Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases of renal or metabolic changes.
This product should not be used for longer than is necessary to correct and sustain circulating volume. Inappropriate/excessive use may worsen or create a metabolic acidosis.
The solution should be warmed to approximately 37ºC prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

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

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interactions:
Caution should be taken if the infusion is administered concomitantly with drugs known to cause sodium retention (e.g. corticosteroids).
Concurrent administration of colloids will require a reduction in dose.

Overdose:
Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation hyperhydration and metabolic acidosis.

*Clinical signs:*
Restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist rales, coughing, protrusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.

*Treatment:*
In these cases, the rate of infusion should be drastically reduced or even discontinued.
Close monitoring of the animal is needed. Cardiovascular overload and pulmonary or cerebral oedema can be avoided by observing the maintenance of a proper diuresis. In case oedema occurs, the rate of infusion should be reduced or the infusion should be stopped. Supportive measures should be applied.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 7. Adverse events

Target species: cattle, horses, sheep, goats, pigs, dogs and cats.

| | |
|---|---|
| Undetermined frequency (cannot be estimated from the available data) | risk of thrombosis |

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. Dosage for each species, routes and method of administration

Intravenous use. Topical use for wound irrigation and moistening of compresses.

*Maximum daily dosage for intravenous use:*
The dosage should be adjusted individually by the veterinarian upon the clinical condition of the animal.
*Maximum infusion rate:*
Generally, it is recommended that the infusion rate should be adapted to the existing fluid deficit. Higher infusion rates are required in case of hypovolaemic shock (dog: up to 100 ml/kg b.w./h; cat: up to 60 ml/kg b.w./h; horse, cattle, neonate calf: 50 to 80 ml/kg b.w./h). Although no specific maximum infusion rates for small ruminants and pigs are available in the scientific literature, there is evidence that those applicable to cattle can be used safely. In case of long-term intravenous infusion therapy 5 to 10 ml/kg b.w./h should normally not be exceeded. However, in some cases, it may be necessary to increase the infusion rates above these levels.
During rapid intravenous fluid administration the animals should be monitored for signs of fluid overload (principally pulmonary oedema).

*General guidelines on fluid intake:*
The dosage of infusion solutions should always be adapted according to the existing fluid requirement of the animal. The total deficit replacement volume results from the amount of maintenance volume plus the amount of deficit volume. The ***maintenance volume*** corresponds to the normal fluid losses due to perspiration, sweating, urine and faeces minus the amount of water which is generated in the intermediary metabolism. Under normal conditions there are the following recommendations for maintenance volume in adult animals:

| **Body weight (kg)** | **Maintenance volume (ml/kg b.w./d)** |
|---|---|
| < 5 | 80 to 120 |
| 5 to 20 | 50 to 80 |
| 20 to 100 | 30 to 50 |
| > 100 | 10 to 30 |

An ***existing fluid deficit*** due to fever, diarrhoea, haemorrhage, vomiting or an absolute and relative intravasal volume deficit must be replaced by an additional fluid intake, depending on the dehydration degree:

| Dehydration degree (% of b.w.) | Deficit volume (mL/kg b.w./d) |
|---|---|
| Slight (4 to 6%) | 40 to 60 |
| Moderate (6 to 8%) | 60 to 80 |
| Severe (> 8%) | > 80 (to 120) |

## 9. Advice on correct administration

The dosage and duration of intravenous treatment must be adjusted according to the specific fluid and electrolyte requirements under control of a veterinarian to prevent any possible side effects due to overdose.
High infusion rates should be avoided in cases of chronic hyponatraemia. All the relevant aseptic precautions must be maintained during intravenous or topical administration. Do not use Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion if you notice that the solution is not clear, free from visible particles, and the container is undamaged.

## 10. Withdrawal periods

Zero days.

## 11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: use immediately after opening the package.
Dispose of any unused product.

## 12. Special precautions for disposal

Medicines should not be disposed of via wastewater
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.

## 13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

## 14. Marketing authorisation numbers and pack sizes

Marketing authorisation number: Vm 03551/3000

Cardboard boxes containing polyethylene containers with:
- 20 x 100 ml
- 20 x 250 ml
- 10 x 500 ml
- 10 x 1000 ml

Not all pack sizes may be marketed.

## 15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

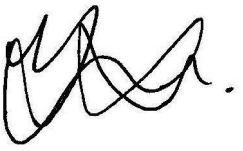
## 16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
B. Braun Melsungen AG
Carl-Braun Strasse 1
D- 34212 Melsungen,
Germany

Manufacturer responsible for batch release:
B. Braun Melsungen AG
Carl-Braun Strasse 1
34209 Melsungen,
Germany

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

## 17. Other information



Approved: 05 June 2023