

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each of 100 ml of solution for infusion contains:

Active substance:

Sodium chloride 0.9 g

Electrolyte concentration

Sodium 154 mmol/l

Chloride 154 mmol/l

Theoretical osmolarity 308 mOsm/l

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion

Clear, colourless aqueous solution, free of particles in suspension

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

The veterinary medicinal product is used in the target species in the following situations:

- 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

4.3 Contraindications

Do not use in animals with:

- Hypertonic dehydration
- Hypernatraemia
- Hyperchloraemia

- Hyperhydration
- Acidosis
- Syndrome of oedema and ascites
- In cases when sodium restriction are indicated

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

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 37°C 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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Intravenous infusion carries a risk of thrombosis.

Please see section 4.10 for symptoms of overdose.

4.7 Use during pregnancy, lactation or 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

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.

4.9 Amounts to be administered and administration route

Administration by intravenous route. Topical use for wound irrigation and moistening of compresses.

The dosage and duration of 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 unless the solution is clear, free from visible particles, and the container is undamaged.

Maximum daily dosage:

The dosage should be adjusted individually by the veterinary 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.

The animals should be monitored for signs of fluid overload (principally pulmonary oedema) during rapid intravenous fluid administration.

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 |

If there is an **existing fluid deficit** due to fever, diarrhoea, haemorrhage, vomiting or an absolute and relative intravascular volume deficit, it 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) |
|---------------|---------------|

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

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, protusion 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.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolyte solutions
ATC vet code: QB05BB01

5.1 Pharmacodynamic properties

This veterinary medicinal product is an isotonic solution containing sodium and chloride with an osmolarity of 308 mOsm/l. Sodium is the major cation of the extracellular space and regulates the size of this space together with other anions.

The sodium content and the fluid homeostasis of the body are closely related. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.

An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolarity.

A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space.

5.2 Pharmacokinetic particulars

Due to the intravenous application, the bioavailability of sodium chloride is 100%.

Sodium and chloride are normal components of the body and their balance is maintained by the kidneys. The sodium level of the veterinary medicinal product is similar to the physiological level in the serum.

The kidneys are the major regulator of the sodium and water balance. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system,

antidiuretic hormone), the kidneys are primarily responsible for the maintenance of a constant volume of the extracellular space and regulation of its fluid composition. Chloride is exchanged for hydrogen carbonate in the tubule system. Thus, it is involved in the regulation of the acid-base balance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Major Incompatibilities

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

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.
Dispose of any unused product.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Immediate packaging: Polyethylene bottles

Cardboard boxes containing:

- 20 bottles with 100 ml solution for infusion
- 20 bottles with 250 ml solution for infusion
- 10 bottles with 500 ml solution for infusion
- 10 bottles with 1000 ml solution for infusion

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

8. MARKETING AUTHORISATION NUMBER

Vm 03551/4005

9. DATE OF FIRST AUTHORISATION

15 October 2013

10. DATE OF REVISION OF THE TEXT

June 2018

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.**

Approved: 14 June 2018

