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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each of 100 ml contains:

Active substance:
Sodium chloride 0.9 g

Excipient:

Qualitative composition of excipients and other constituents
Solvent:
Water for injection

Clear and colourless solution, free from particles.

Electrolyte concentration
Sodium 154 mmol/l
Chloride 154 mmol/l

Theoretical osmolarity 308 mOsm/l
pH 4.5 – 7.0

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each 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

3.3 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

3.4 Special warnings

None.

3.5 Special precautions for use

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:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 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.

3.9 Administration routes and dosage

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

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 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 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.
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 intravasal 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)

3.10 Symptoms of overdose (and where applicable emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

3.12 Withdrawal periods

Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QB05BB01

4.2 Pharmacodynamics

This veterinary medicinal product is an isotonic solution containing sodium and chloride with an osmolarity of 308 mOsml/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.

4.3 Pharmacokinetics

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.
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.
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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

7. MARKETING AUTHORISATION NUMBER

Vm 03551/3000

8. DATE OF FIRST AUTHORISATION

15 October 2013

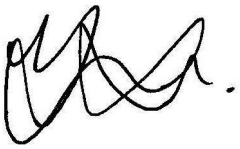
9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

June 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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



Approved: 05 June 2023