SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
Solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contain:

Active substance
Sodium chloride 7.5 g

For a full list of excipients, see section 6.1

Electrolyte concentration:

Na	1283 mmol/l
Cl	1283 mmol/l

3. PHARMACEUTICAL FORM

Solution for infusion.
(A clear, colourless aqueous solution)

Theoretical osmolarity: 2566 mOsm/l
Free from bacterial endotoxins.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indication for use, specifying the target species

Indications for all target animal species:
As adjunctive therapy in the treatment of emergency situations, like haemorrhagic, endotoxic, septic or hypovolaemic shock, when a rapid increase in the plasma circulation volume is required in order to restore or maintain vital organ functions.

4.3 Contraindications

Do not use in animals with:

- Hypertonic hyperhydration;
- Renal insufficiency;
- Severe electrolyte disturbances;

- Uncontrolled haemorrhage;
- Pulmonary oedema;
- Retention of water and sodium chloride;
- Cardiac insufficiency;
- Hypertension;
- Hypertonic dehydration.

4.4 Special warnings for each target species

Excessive administration of chloride may, due the electrolyte's interaction with the body's bicarbonate buffer system, exert an acidifying effect. Therefore, in clinical instances accompanied by acidosis and hyperchloraemia, special care has to be taken if this veterinary medicinal product is infused.

Sodium chloride administration may aggravate a pre-existing hypokalaemia.

Adequate access to drinking water should be provided when using the product.

Animals treated with this veterinary medicinal product should be closely observed for possible deterioration of the clinical condition as a consequence of treatment.

4.5 Special precautions for use

i) Special precautions for use in animals

Any existing haemorrhage should be stopped or controlled before treatment.

The solution should be administered slowly and at body temperature to avoid thermal shock.

In severe cases, the central venous pressure has to be monitored during administration.

Frequent monitoring of the water balance is recommended.

Hypertonic solutions must be administered solely by intravenous route.

Rapid infusion of hypertonic NaCl can lead to myelinolysis in the brain in animals with chronic hyponatraemia.

Care should be taken to avoid the use of excessive doses (> 8 ml/kg body weight) and excessive dose rates (> 60 ml/kg body weight/h).

Repeated infusion should only be performed after checking sodium concentration and acid-base status.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reaction (frequency and seriousness)

An excess of sodium may cause hypokalaemia, which may be aggravated by the existence of continued loss of potassium and hyperchloraemia.

Erroneous administration of sodium to dehydrated animals may increase the existing extracellular hypertonia, with aggravation of existing disorders, and may cause death.

Rapid infusion may cause oedema, principally pulmonary oedema, especially in case of concurrent cardiac or renal insufficiency. After rapid administration, hypotension, arrhythmias, haemolysis, haemoglobinuria, bronchoconstriction as well as hyperventilation may occur.

Administration into small peripheral veins may cause signs of pain.
Infusion of hypertonic sodium chloride may provoke diuresis with formation of hypertonic urine.

A risk of thrombosis should be considered.

4.7 Use during pregnancy and lactation or lay

In the absence of data on target species, use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Administer with care to animals that have had prolonged treatment with corticosteroids having a mineralocorticoid action.

4.9 Amounts to be administered and administration route

Intravenous use.

The recommended dosage is 3 to 5 ml/kg body weight which have to be administered over a period of maximum 15 minutes, without exceeding a rate of 1 ml/kg body weight/min. Administration of hypertonic sodium chloride should be followed by infusion of isotonic fluids over one or two hours in order to restore the hydration state of the interstitial space.

Under the control of a veterinarian the dosage should be adjusted to meet the specific evolving demands of the animal under treatment.

Maintain aseptic precautions during administration.
Do not use if container or closure is damaged.
For single use only. Do not reconnect partially used infusion bottles.
Cloudy solutions or solutions containing visible solid particles should not be administered

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

Overdose of hypertonic sodium chloride solution may lead to an increase in the extracellular volume (extracellular hyperhydration).

Hyperhydration is manifest by agitation and hypersalivation: in these cases, it is appropriate to reduce the rate of infusion drastically or to stop the infusion.

Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis and to avoid causing cardiovascular overload and pulmonary or cerebral oedema.

Fluid output, plasma sodium concentration and blood pressure should be monitored. If hypernatraemia is present, it should be corrected slowly, using water orally if possible, or intravenous 0.9% sodium chloride solution, or for less severe hypernatraemia, an intravenous isotonic electrolyte solution with a low sodium chloride concentration.

If the solution is exclusively administered in large doses, the chloride ions displace bicarbonate ions and induce an acidosis.

An increase of serum osmolarity over 350 mOsm/l may produce cerebral dysfunction and coma.

Overdose of the veterinary medicinal product can cause hypernatraemia.

4.11 Withdrawal periods

Meat and offal:zero days
Milk zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Solutions affecting the electrolyte balance, electrolytes
ATCVet code: QB05BB01

5.1 Pharmacodynamic properties

Infusion of a hypertonic saline solution leads to an osmotic expansion of the plasma and a shift increase of the volume of the plasma from the interstitial fluid.

The solution is used as adjunctive therapy in the treatment of circulatory shock. It is intended to provide an interim boost to cardiovascular function, pending restoration of the circulatory volume by conventional isotonic intravenous rehydration solutions. It is intended to improve cardiac output and cause a favourable redistribution of blood flow to the renal and visceral circulation, in particular.

This solution, after administering into the body, produces an increase in plasma crystalloid osmotic pressure, and then the water flows from the interstitial compartment to the vascular and the salt to the interstitial fluid, so that the

extracellular fluid is hypertonic. As a result, the water passes from cell to the extracellular fluid, thus increasing the volume of it, decreasing the intracellular fluid. Then the crystalloid concentration and the osmotic pressure or osmolality of all body fluids are increased.

5.2 Pharmacokinetic particulars

The kidneys excrete excess sodium and chloride, particularly by reducing the secretion of aldosterone, resulting in the elimination of hypertonic urine. Hypertonia of the extracellular fluid stimulates osmoreceptors with increased secretion of antidiuretic hormone, which reduces the diuresis.

Hypertonia of the intracellular fluid causes thirst, so the animal will drink until the normal osmotic pressure or osmolality of the body is restored.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

Solutions containing sodium chloride are incompatible with Amphotericin B, which is easily oxidized.
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: it should be used immediately. Do not reuse the package once it is opened. Dispose of any unused product.

6.4 Special precautions for storage

Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Low density polyethylene bottles of 500 ml of capacity.

Pack sizes:
Cardboard boxes containing:
1 bottle with 500 ml solution for infusion
10 bottles with 500 ml solution for infusion

Not all pack sizes may be marketed.

Closure:
the container is hermetically closed before the closure system is applied.
The additional closure cap on top of the sealed polyethylene container is made from polyethylene. Between the container and the closure cap an elastomeric disk is placed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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
Hessen
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 03551/4003

9. DATE OF FIRST AUTHORISATION

21 October 2009

10. DATE OF REVISION OF THE TEXT

December 2019

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only – to be supplied only on veterinary prescription.

Approved: 24 December 2019