SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Sodium chloride 72 mg

Approximate ionic content in millimoles per litre:
Sodium 1232 mmol/litre
Chloride 1232 mmol/litre

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, calves, horses, dogs and cats.

4.2 Indications for use, specifying the target species

In all target species:
As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

4.3 Contraindications

Do not use in animals with:
- Hypertonic hyperhydration (characterised by oedema);
- Renal insufficiency;
- Severe electrolyte disturbances;
- Uncontrolled haemorrhage;
- Pulmonary oedema;
- Retention of water and sodium chloride;
- Cardiac insufficiency;
- Hypertension;
- Hypertonic dehydration (characterised by thirst).

4.4 Special warnings for each target species

Excessive administration of chloride may, due to the electrolytes' 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 to be infused.
Sodium chloride administration may aggravate a pre-existing hypokalaemia.
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

Special precautions for use in animals

Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

Maintain aseptic precautions.

Administration of the solution must be accompanied by an opportunity for the animal to drink *ad libitum*.

This veterinary medicinal product should ideally 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.

Any existing haemorrhage should be stopped or controlled before treatment.

Hypertonic solutions must be administered solely by the intravenous route.

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

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

Do not use the product as a vehicle for the administration of other veterinary medicinal products.

Care should be taken to avoid the use of excessive doses (>8 ml/kg) and excessive dose rates (>1 ml/kg/minute).

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

None.

4.6 Adverse reactions (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 cases 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, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment of 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 mineralcorticoid action.

4.9 Amounts to be administered and administration route

Intravenous use.

The infusion should ideally be warmed to approximately 37°C prior to administration.

Recommended doses are in the range 4-8 ml/kg, and an infusion rate of 1 ml/kg/minute should not be exceeded.

The veterinary medicinal product should be used in conjunction with conventional fluid therapy. The administration of the product is usually followed by the intravenous administration of an isotonic intravenous fluid (e.g. an intravenous 0.9% sodium chloride solution).

Adequate access to drinking water should also be provided.

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.

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 period(s)

Meat and offal:	Zero days
Milk:	Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes.
ATC vet code: QB05BB01.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Intravenous infusion ensures rapid distribution.
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 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: 2 years.

This veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and unused contents should be discarded.

6.4 Special precautions for storage

Do not store above 25°C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Polyvinylchloride infusion bag overwrapped with polypropylene.
Pack sizes: Individual fluid bags of 500 ml, 3000 ml and 5000 ml, each supplied with a package leaflet, or boxes containing 20 x 500 ml, 4 x 3000 ml or 2 x 5000 ml.

Not all pack sizes may be marketed.

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

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 50406/5038

9. DATE OF FIRST AUTHORISATION

16 November 2017

10. DATE OF REVISION OF THE TEXT

April 2025

Gavin Hall
Approved: 25 April 2025