SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 72 mg/ml solution for infusion for cattle, cattle (calves), horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium chloride 72 mg

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

Excipients:

Qualitative composition of excipients and other constituents
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, cattle (calves), horses, dogs and cats.

3.2 Indications for use for each target species

As adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic).

3.3 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).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

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

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 veterinary medicinal 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).

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 hyperchloremia, special care has to be taken if this veterinary medicinal product is to be infused.
Sodium chloride administration may aggravate a pre-existing hypokalaemia.

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.

3.6 Adverse events

Cattle, cattle (calves), horses, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Death[a]
Undetermined frequency (cannot be estimated from the available data)	Hypokalaemia[b], Haemolysis[c], Haemoglobinuria[c] Oedema[c, d] Hypotension[c], Arrhythmia[c] Pulmonary oedema[c,d], Respiratory tract disorder[c,e], Hyperventilation[c] Polyuria[f] Thrombosis Injection site pain[g]

[a] Due to erroneous administration of sodium to dehydrated animals which may increase the existing extracellular hypertonia, with aggravation of existing disorders.
[b] May be induced by an excess of sodium and may be aggravated by the existence of continued loss of potassium and hyperchloraemia.
[c] After rapid administration.
[d] Especially in cases of concurrent cardiac or renal insufficiency.
[e] Bronchoconstriction.
[f] With formation of hypertonic urine.
[g] Administration into small peripheral veins may cause signs of pain.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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.

3.8 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.

3.9 Administration routes and dosage

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 veterinary medicinal product is usually followed by the intravenous administration of an isotonic intravenous fluid (e.g. an intravenous 0.9 % sodium chloride solution).
Fluid output, plasma sodium concentration and blood pressure should be monitored.

Adequate access to drinking water should also be provided.

Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis.

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

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 needed to avoid causing cardiovascular overload and pulmonary or cerebral oedema.

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

Overdose of the veterinary medicinal product can cause hypernatraemia. 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.

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: Zero days;
Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QB05BB01.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

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: 2 years.
Shelf life after first opening the immediate packaging: use immediately.

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Polyvinyl chloride (PVC) infusion bags sealed individually in a polypropylene over-wrap with one additive addition port (PVC) and one twist-off administration port (PVC).
Individual fluid bags are supplied with a package leaflet each, or in multi packs in boxes.

Pack sizes:
Infusion bag with 500 ml solution for infusion.
Infusion bag with 3000 ml solution for infusion.
Infusion bag with 5000 ml solution for infusion.
Box with 15 x 500 ml infusion bags with solution for infusion.
Box with 20 x 500 ml infusion bags with solution for infusion.
Box with 3 x 3000 ml infusion bags with solution for infusion.
Box with 4 x 3000 ml infusion bags with solution for infusion.
Box with 2 x 5000 ml infusion bags with solution for infusion.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 50406/3033
Vm 50406/5038

8. DATE OF FIRST AUTHORISATION

16 November 2017

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 11 November 2025

Gavin Hall