SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hypertonic 7.2% w/v solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Sodium chloride 7.2% w/v

Approximate ionic content in millimoles per litre:

Sodium	1232	mmol/L
Chloride	1232	mmol/L

Excipients:
For a 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

This product is administered by intravenous infusion as adjunctive therapy in the treatment of circulatory shock (hypovolaemic or endotoxaemic) in cattle, calves, horses, dogs and cats.

4.3 Contraindications

Do not administer to hypernatraemic animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Maintain aseptic precautions.

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

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

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

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Excessive doses and/or dose rates can cause hypernatraemia, hypotension, bradycardia, bronchoconstriction and hyperventilation.

Sodium overload may occur particularly in animals with cardiac or renal impairment, and it should be noted that sodium excretion may be impaired post-surgery/trauma. It should also be noted that hypernatraemia may occur in animals that are dehydrated.

A risk of thrombosis with intravenous infusion should be considered.

4.7 Use during pregnancy and lactation or lay

Use under veterinary supervision.

4.8 Interaction with other veterinary medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

Intravenous administration.

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

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

Recommended doses are in the range 4-8 ml/kg, and an infusion rate of 60 ml/kg/hr should not be exceeded.

Hypertonic saline (7.2% w/v) should be used in conjunction with conventional fluid therapy. The administration of hypertonic saline 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

Excessive doses and/or dose rates can cause hypernatraemia, hypotension, bradycardia, bronchoconstriction and hyperventilation.

4.11 Withdrawal periods

Meat and offal: Zero days.
Milk: Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes
ATCvet 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 constituents of the infusion solution will be metabolised and excreted through the same pathways as those substances derived from normal dietary sources.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

It is generally recommended the no agents should be added to the solution.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Presented in clear polyvinylchloride (PVC) infusion bags, over-wrapped with polypropylene, in cartons of 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 2000 ml, 4 x 3000 ml and 2 x 5000 ml.

Not all pack sizes may be marketed.

Each carton contains sufficient number of package leaflets so that individual units may be supplied.

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 Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4056

9. DATE OF FIRST AUTHORISATION

18 December 1998

10. DATE OF REVISION OF THE TEXT

June 2016

Approved: 03 June 2016