Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ISOLEC 1 (Sodium Chloride 0.9 % w/v Intravenous Infusion BP (Vet)).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride 0.9 % w/v

Approximate ionic content in millimoles per litre:
Sodium 150 mmol/L
Chloride 150 mmol/L

3 PHARMACEUTICAL FORM

Solution for infusion.
Clear, colourless solution for infusion.

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 for the treatment of dehydration in cattle, calves, horses, dogs and cats. It may be used to correct hypovolaemia resulting from shock or gastrointestinal disease (especially where metabolic alkalosis is present, e.g. in cases of sustained vomiting or abomasal disorders in cattle). It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Sodium overload may occur in animals with cardiac or renal impairment. It should be noted that sodium excretion may be impaired post-surgery/trauma.

A risk of thrombosis with intravenous infusion should be considered.

The product should be warmed to approximately 37^{o}C prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.

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.

Maintain aseptic precautions.

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

No special precautions required.

Other precautions

No special precautions required.

4.6 Adverse reactions (frequency and seriousness)

Excessive infusion rates can cause restlessness, moist lung sounds, tachycardia, tachypnoea, nasal discharge, coughing, vomiting and diarrhoea.

4.7 Use during pregnancy, lactation or lay

Use under veterinary supervision.

4.8 Interaction with other medicinal products and other forms of interaction

No known interactions.

4.9 Amounts to be administered and administration route

Administer by intravenous infusion

The volume and rate of infusion will depend upon the clinical condition, existing deficits of the animal, maintenance needs and continuing losses.

Generally aim to correct hypovolaemia by 50 % initially (ideally over 6 hours but faster if necessary) and reassess by clinical examination.

Deficits are generally in the range of 50 ml/kg (mild) to 150 ml/kg (severe). An infusion rate of 15 ml/kg/hour is recommended in the absence of shock (range 5-75 ml/kg/hour).

In shock, high initial infusion rates, up to 90 ml/kg/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless urine output is restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.

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

Monitor fluid output. The administration of a diuretic may be necessary.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QB05BB01 Electrolytes

5.1 Pharmacodynamic properties

The intravenous infusion is used to replace depleted water and electrolytes when fluids cannot be given orally. It will restore extracellular volume (including plasma volume) and, where metabolic alkalosis is present, it will help to correct it.

5.2 Pharmacokinetic properties

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

None known.

6.3 Shelf-life

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

Unopened
100 ml: 18 months.
250 ml, 500 ml, 1000 ml, 2000 ml, 3000 ml and 5000 ml: 2 years.

After opening
The product does not contain an antimicrobial preservative. It is intended for single use only and any 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

Presented in clear polyvinylchloride (PVC) infusion bags, over-wrapped with clear polypropylene, in cartons of 50 x 100 ml, 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 products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

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Dechra House,
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8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10799/013/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18th April 2008

10 DATE OF REVISION OF THE TEXT

June 2013