SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetivex 9 (Ringer's Solution for Infusion)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Sodium chloride	0.860 % w/v
Potassium chloride	0.030 % w/v
Calcium chloride dihydrate	0.033 % w/v

Approximate ionic content in millimoles per litre:

Sodium	147 mmol/l
Potassium	4 mmol/l
Calcium	2.25 mmol/l
Chloride	155.5 mmol/l

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

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 volume depletion resulting from shock or gastrointestinal disease, especially where hypokalaemia is present (e.g. in cases of sustained vomiting).

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

Ringer's Solution for Infusion should 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.

This product should be used with caution in animals with cardiac or renal impairment as sodium overload may occur.

Maintain aseptic precautions.

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

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

There is a risk of thrombosis with intravenous infusion.

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

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

None known.

4.9 Amounts to be administered and administration route

Ringer's Solution for Infusion should ideally be warmed to approximately 37°C prior to administration.

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.

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.

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

Monitor fluid output. Administration of a diuretic may be necessary.

4.11 Withdrawal periods

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes
ATC Vet Code: QB05BB01

5.1 Pharmacodynamic properties

This product replaces depleted water and electrolytes when administered via the intravenous route. It will restore extracellular volume and, where metabolic alkalosis is present, it will help to correct it.

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 sources.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

None known.

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 polyvinylchloride (PVC) infusion bags, overwrapped with 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 product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4054

9. DATE OF FIRST AUTHORISATION

17 November 1998

10. DATE OF REVISION OF THE TEXT

October 2015

Approved: 22 October 2015