SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetivex 3 (Sodium Chloride 0.9% w/v and Glucose 5% w/v Infusion BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Sodium chloride	0.9 % w/v
Glucose monohydrate	5.5 % w/v
(equivalent to anhydrous glucose 5.0 % w/v)	

Approximate ionic content in millimoles per litre:

Sodium	150 mmol/L
Chloride	150 mmol/L

For the full list of excipients, see section 6.1

Each one litre provides approximately 200 kcal.

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

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. It may be administered to meet normal fluid and electrolyte requirements when fluids cannot be given orally. The glucose is not a significant calorie source but can provide transient improvement of hypoglycaemia.

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

Infusion rates should not exceed 10ml/kg/hour to minimise the risk of glycosuria and osmotic diuresis.

Administration of this product to diabetic animals must be conducted with extreme caution.

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

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.

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

Administer by intravenous infusion at a rate not exceeding 10 ml/kg/hour.

The product should ideally be warmed to approximately 37^{o}C prior to 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.

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 with carbohydrates
ATCvet code: QB05BB02

5.1 Pharmacodynamic properties

The solution is used to replace depleted water and electrolytes and as a temporary source of glucose for animals who cannot be given fluids orally.

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

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
100 ml: 18 months
250 ml, 500 ml, 1000 ml, 2000 ml, 3000 ml and 5000 ml: 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, over-wrapped 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
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4055

9. DATE OF FIRST AUTHORISATION

10 December 1998

10. DATE OF REVISION OF THE TEXT

October 2015

Approved: 22 October 2015