

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetivex 18
(Sodium chloride 0.18 % w/v and Glucose 4 % w/v intravenous solution for infusion BP (Vet))

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Sodium chloride 0.18 % w/v
Glucose monohydrate 4.4 % w/v
(equivalent to anhydrous glucose 4.0 % w/v)

Approximate ionic content in millimoles per litre:
Sodium 30 mmol/L
Chloride 30 mmol/L

Each one litre provides approximately 150 kcal.

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 for maintenance therapy of dehydration in cattle, calves, horses, dogs and cats. It should be used once the underlying fluid balance has been restored.

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

The solution 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.

This product should not be used for prolonged periods of time unless there is continuing excessive loss of electrolytes, as it may provoke hypokalaemia.

Special precautions to be taken by the person administering the 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 medicaments 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.

The solution 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, recommended dose for maintenance therapy:
50 ml per kg body weight per day.

The infusion rate should be decreased in the presence of cardiac and pulmonary disease.

The maximum recommended infusion rate is 12 ml/kg/hour, otherwise it is liable to cause glycosuria and osmotic diuresis. .

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

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

4.11 Withdrawal periods

Meat and offal:	Zero days
Milk:	Zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes with carbohydrates.
ATC Vet Code: QB05BB02.

5.1 Pharmacodynamic properties

The solution is used as a source of water, glucose and electrolytes for animals that 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

Check compatibility of additives prior to administration.

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

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, 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
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Keighley Road
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8. MARKETING AUTHORISATION NUMBER

Vm 10434/4058

9. DATE OF FIRST AUTHORISATION

09 December 1998

10. DATE OF REVISION OF THE TEXT

June 2016

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