Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetivex 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Sodium Lactate	3.20 mg
Sodium Chloride	6.00 mg
Potassium Chloride	0.40 mg
Calcium Chloride	0.20 mg

(equivalent to Calcium Chloride Dihydrate: 0.27 mg)

Sodium: 131 mmol/litre
Potassium: 5 mmol/litre
Calcium: 2 mmol/litre
Bicarbonate (as lactate): 29 mmol/litre
Chloride: 111 mmol/litre

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, horses, dogs and cats.

4.2 Indications for use, specifying the target species

This veterinary medicinal product is administered by intravenous infusion for the treatment of dehydration and metabolic acidosis in cattle, horses, dogs and cats. It may be used to correct volume depletion (hypovolaemia) resulting from gastrointestinal disease or shock.

4.3 Contraindications

Do not use in animals with:
- hyperkalaemia
- hypercalcaemia
- hypernatraemia
- hyperlactataemia
- hyperhydration
- metabolic alkalosis
- oedema (hepatic, renal, or cardiac)
- Addison's disease

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use unless the solution is clear, free from visible particles, and the container is undamaged.
A risk of thrombosis with intravenous infusion should be considered. Maintain aseptic precautions.
This veterinary medicinal product 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 veterinary medicinal product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.
Use of this solution requires monitoring of the clinical and physiological status of the animal especially in cases of:
- severe renal impairment
- cardiac impairment
- sodium retention with oedema
- treatments with corticosteroids and their derivatives.

This veterinary medicinal product should be used with caution in animals with cardiac or renal impairment as sodium overload may occur. It should be noted that sodium excretion may be impaired post-surgery/trauma.
Monitor serum potassium and serum calcium in treated animals, particularly potassium levels in cases at risk of hyperkalaemia, such as during chronic renal failure.
In animals with hepatic impairment, the product may not produce its alkalising action since lactate metabolism may be altered.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

4.6 Adverse reactions (frequency and seriousness)

Skin reactions (urticarial, eczema, skin lesions) and allergic oedema are very rarely observed.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animal treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

This veterinary medicinal product is incompatible with methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions.
Interactions linked to calcium.
In case of concomitant blood transfusion, the product should not be administered with the blood in the same infusion set due to the risk of clotting. This veterinary medicinal product contains calcium. Do not add drugs to this solution that may bind (chelate) to calcium.

4.9 Amounts to be administered and administration route

Intravenous use.
The 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 renal function and urine

output are 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

In the presence of volume overload signs (e.g. restlessness, moist lung sounds, tachycardia, tachypnoea, nasal discharge, coughing, vomiting and diarrhoea), treatment should involve administering diuretics and stopping the infusion. An excessive infusion of product may cause metabolic alkalosis due to the presence of lactate ions.

4.11 Withdrawal period(s)

Meat and offal: zero days.
Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes
ATCvet code: QB05BB01

5.1 Pharmacodynamic properties

Isotonic crystalloid solutions are for vascular filling and electrolyte replacement. They have an ionic composition very close to the extracellular fluid.
Sodium is the major cation of extracellular fluid. It is responsible for maintaining the volume of liquid and extracellular osmolarity.
Potassium is mainly an intracellular cation.
99% of calcium is present in the skeleton. Chloride is essentially an extracellular anion.
Lactate produces bicarbonate salts (hence its alkalising effect).

5.2 Pharmacokinetic particulars

The solution diffuses into the extracellular space whose volume is increased accordingly.
The lactate ion is rapidly metabolised by the liver where it is converted to pyruvate used in the Krebs cycle with production of bicarbonates.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Hydrochloric acid, dilute (for pH-adjustment)

6.2 Major incompatibilities

This veterinary medicinal product is incompatible with methylprednisolone, and sodium lactate or sodium bicarbonate intravenous infusions.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
The veterinary medicinal product should be used immediately and not stored after opening.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polyvinylchloride infusion bags overwrapped with polypropylene.
All pack sizes have two ports. In place of the additive port on the 5000 ml combi pack is a combi port. This enables two such bags to be connected in sequence and volumes greater than 5000 ml to be administered during one infusion.
Pack sizes: Individual fluid bags of 250 ml, 500 ml, 1000 ml, 3000 ml, 5000 ml and 5000 ml combi, each supplied with a package leaflet, or boxes containing 20 x 250 ml, 20 x 500 ml, 10 x 1000 ml, 4 x 3000 ml, 2 x 5000 ml, 2 x 5000 ml combi. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 Regulatory B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/022/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 August 2013
Date of latest renewal: 01 June 2018

10 DATE OF REVISION OF THE TEXT

January 2019