[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VETIVEX 11 (Hartmann's) solution for infusion for cattle, horses, dogs and cats [UK, IE]
VETIVEX Ringer Lactate Solution for infusion for cattle, horses, dogs and cats [BE, FR, NL]
INFUSOLEC solution for infusion for cattle, horses, dogs and cats [DE, DK, SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substances:

Sodium Lactate	3.17 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 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, 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 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

Lactate-containing solutions will not be utilised effectively in animals with hepatic impairment and it is undesirable to use this product in animals with metabolic alkalosis.

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 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 product does not contain an antimicrobial preservative. It is intended for single use only and any unused contents should be discarded.
This product should be used with caution in animals with cardiac or renal impairment as sodium overload may occur.

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

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

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

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)

Monitor fluid output.

4.11 Withdrawal periods

Cattle and horses: Meat and offal / milk – zero days / hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Electrolytes, ATCvet code: QB05BB01

5.1 Pharmacodynamic properties

This product replaces depleted water and electrolytes when administered via the intravenous route, to correct water imbalance in dehydration, and restore electrolyte and acid-base balance. It will restore plasma volume and correct metabolic acidosis, as the hepatic metabolism of lactate yields bicarbonate slowly enough to prevent a counter-imbalance of alkalosis.

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
Hydrochloric acid, dilute (for pH-adjustment)

6.2 Incompatibilities

This 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 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 product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
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8. MARKETING AUTHORISATION NUMBERS

Vm 10434/4080
VPA 10799/025/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

UK: 20 June 2013
IE: 09 August 2013

10 DATE OF REVISION OF THE TEXT

November 2015