

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Isolec 11 Solution for Infusion.

(Compound Sodium Lactate Intravenous Infusion BP (Vet)) (Hartmann's Solution).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium lactate	0.317 % w/v
----------------	-------------

Sodium chloride	0.600 % w/v
-----------------	-------------

Potassium chloride	0.040 % w/v
--------------------	-------------

Calcium chloride dihydrate	0.027 % w/v
----------------------------	-------------

Approximate ionic content in millimoles per litre:

Sodium	131	mmol/L
--------	-----	--------

Potassium	5	mmol/L
-----------	---	--------

Calcium	2	mmol/L
---------	---	--------

Bicarbonate (as lactate)	29	mmol/L
--------------------------	----	--------

Chloride	111	mmol/L
----------	-----	--------

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion.

Clear colourless solution for infusion.

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 and metabolic acidosis in cattle, calves, 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

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.

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.

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

No special precautions required.

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

See 6.2.

4.9 Amounts to be administered and administration route

For intravenous administration.

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

Monitor fluid output.

4.11 Withdrawal Period(s)

Cattle: meat - zero days

Cattle: milk - zero days

Horses: meat - zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QB05BB01 Electrolytes

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection

Hydrochloric acid, dilute

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:

100 ml packs: 18 months

250 ml, 500 ml, 1000 ml, 2000 ml, 3000 ml, and 5000 ml packs: 2 years

6.4 Special precautions for storage

Do not store above 25⁰C

Do not freeze.

Use immediately. This product does not contain an antimicrobial preservative. For single use only. Discard unused contents.

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 2000ml, 4 x 3000 ml, and 2 x 5000 ml.

Not all pack sizes may be marketed.

All pack sizes have two ports. In place of the additive port on the 5000 ml Isolec 11 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-on-Trent
Staffordshire
ST7 1XW
UK

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10799/012/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26th November 2008

10 DATE OF REVISION OF THE TEXT

August 2013