# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care Hartmann's Lactated Ringers Solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

100 ml contains:

| | |
|---|---|
| Active substances: | |
| Sodium chloride | 0.600 g |
| Potassium chloride | 0.040 g |
| Calcium chloride dihydrate | 0.027 g |
| Sodium (S)-lactate | 0.312 g |
| (as sodium lactate solution (50% w/v) | 0.624 g) |

For a full list of excipients, see section 6.1

| | |
|---|---|
| Electrolyte concentrations: | |
| Sodium | 130.49 mmol/l |
| Potassium | 5.37 mmol/l |
| Calcium | 1.84 mmol/l |
| Chloride | 111.70 mmol/l |
| Lactate | 27.84 mmol/l |

## 3 PHARMACEUTICAL FORM

Solution for infusion
Clear, colourless, aqueous and free from bacterial endotoxins.

| | |
|---|---|
| Theoretical osmolarity | 277mOsm/1 |
| Titration acidity | < 1 mmo1/1 |
| pH | 5.0 - 7.0 |

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, horses, sheep, goats, pigs, dogs and cats

### 4.2 Indications for use, specifying the target species

Indication for all target animal species:

- Isotonic dehydration
- Metabolic acidosis
- Hypotonic dehydration
- Maintenance of normal extracellular fluid levels
- Electrolyte replacement in burns

## 4.3 Contraindications

Do not use in animals with:
- Alkalosis of any origin
- Oedema (hepatic, renal, or cardiac)
- Overhydration
- Hyperkalaemia, hypernatraemia, hyperlactataemia
- Hepatic insufficiency

## 4.4 Special warnings for each target species

None.

## 4.5 Special precautions for use

**Special precautions for use in animals.**

- Before administering this solution the clinical and biological data of the animal have to be carefully examined.

- Monitoring of serum electrolyte levels should be obliged in cases of electrolyte imbalances, such as hypertonic or hypotonic dehydration, or a single increase of one electrolyte (e.g. hyperchloraemia) as well. Furthermore monitoring of the acid-balance and the clinical condition of the animal should accompany the treatment with this veterinary medicinal product.

- During use of this veterinary medicinal product, the fluid volume range must be considered. Infusion of larger than necessary volumes may lead to cardiovascular overload and pulmonary oedema.

- This veterinary medicinal product should be used with caution in congestive heart failure, severe renal insufficiency and in animals treated with corticoids and derivates.

- Due to the potassium content of this solution it should be used prudently in severe renal impairment.

- Infusion of this solution containing lactate ions may cause metabolic alkalosis.

- In animals with liver function disorders, the solution may cause acidosis because degradation of lactate into bicarbonate requires an intact liver metabolism.

- Slow infusion into a large blood vessel should be performed under conditions of strict asepsis.

- Do not inject intramuscularly.

- During treatment clinical and biological state of the animal should be monitored.

- The solution should be administered at body temperature. Warm up the solution only by immersion in hot water (< 40 ºC).

**Special precautions to be taken by the person administering the medicinal product to animals.**

Not applicable.

## 4.6 Adverse reactions (frequency and seriousness)

This veterinary medicinal product contains calcium, thus an effect on the heart cannot be ruled out.

## 4.7 Use during pregnancy, lactation or lay

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

## 4.8 Interaction with other medicinal products and other forms of interaction

None known.

## 4.9 Amounts to be administered and administration route

Intravenous use.
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/bw/hour is recommended in the absence of shock (range 5-25 ml/kg/bw/hour).
In shock, high initial infusion rates, up to 90 ml/kg/bw/hour, are needed. High infusion rates should not be continued for longer than 1 hour unless urine output is restored. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.
Do not use if container or closure is damaged.
For single use only.
Solutions containing visible solid particles should not be administered.

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

Overdose may result in cardiovascular overload and pulmonary oedema, which can lead to following symptoms such as restlessness, coughing and polyuria.
In case overdose has occurred the rate of infusion should be drastically reduced or the infusion should be stopped.

## 4.11 Withdrawal Period(s)

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

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Solutions affecting the electrolyte balance
ATCvet code: QB05BB01

## 5.1 Pharmacodynamic properties

The veterinary medicinal product is administered to replace or prevent dehydration, to correct acid-base, fluid and electrolyte abnormalities in different clinical conditions. The electrolytes Na+, K+, Ca2+, Cl- as well as the metabolisable anion lactate are indispensable for the maintenance and correction of fluid and electrolyte homeostasis and acid-base balance. All substrates are occurring during normal physiological metabolism.

## 5.2 Pharmacokinetic properties

Due to intravenous administration the bioavailability of the active substances is 100%.
The metabolism of this veterinary medicinal product corresponds to each of its components: Na+, K+, Ca2+, Cl-, and lactate.
Sodium lactate decomposes into bicarbonate, which later is converted into pyruvate that is used in the Krebs tricarboxylic cycle.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Water for injections.

## 6.2 Incompatibilities

This veterinary medicinal product is incompatible with Chlortetracycline, Amphotericin B and Oxytetracycline.

Mixtures with additives and other drugs (e.g. oxalate-, phosphate- and carbonate-/hydrogen carbonate- containing ones) may cause incompatibilities.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## 6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale:
Plastic bottle: 3 years
Plastic bag: 3 years

Use immediately after opening the immediate package.

Dispose of any unused product.

## 6.4 Special precautions for storage

Protect from light.
Keep the bottle and the plastic bag in the outer carton.
Do not refrigerate or freeze.

## 6.5 Nature and composition of immediate packaging

Low density polyethylene bottles of 500 and 1000 ml. The container is hermetically closed before the closure system is applied. The additional closure cap on top of the sealed polyethylene container is made from polyethylene. Between the container and the closure cap an elastomeric disk is placed.

Three-laminate plastic bag (polypropylene inner layer) of 5000 ml. The bag is equipped with a connection port for an infusion set and with an injection port. The ports are sealed by polypropylene caps with halogenbutyl rubber stoppers.

Pack sizes:
Cardboard boxes containing:
10 bottles with 500 ml solution for infusion
10 bottles with 1000 ml solution for infusion
2 bags with 5000 ml solution for infusion

Not all pack sizes may be marketed.

## 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

B. Braun Melsungen AG
Carl-Braun-Strasse 1
34212 Melsungen
Germany

Postal Address:
34209 Melsungen
Germany

# 8 MARKETING AUTHORISATION NUMBER(S)

VPA 10465/003/001

# 9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th August 2010

Date of last renewal: 1st May 2015

# 10 DATE OF REVISION OF THE TEXT