1. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care Hartmann's Lactated Ringers Solution for infusion for cattle, horse, sheep, goat, pig, dog and cat.

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)

Excipient:

Qualitative composition of excipients and other constituent
Water for injections

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

Clear, colourless, aqueous and free from bacterial endotoxins.

Theoretical osmolarity	277 mOsm/l
Titration acidity	< 1 mmol/l
pH	5.0 - 7.0

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Indication for all target animal species:

- Isotonic dehydration
- Metabolic acidosis
- Hypotonic dehydration

- Maintenance of normal extracellular fluid levels
- Electrolyte replacement in burns

3.3 Contraindications

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

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

- 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 veterinary medicinal product to animals:

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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

Undetermined frequency (cannot be estimated from the available data)	Cardiac disorder[1]

[1]Due to the calcium content, effect on the heart cannot be ruled out.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.
To ensure a correct dosage, body weight should be determined as accurately as possible.
Do not use if container or closure is damaged.
For single use only.
Solutions containing visible solid particles should not be administered.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance:

Not applicable.

3.12 Withdrawal periods

Dogs and cats: Not applicable.

Cattle, horses, sheep, goats, pigs: Meat and offal: zero days.
Cattle, horses, sheep, goats: Milk: zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QB05BB01

4.1 Pharmacodynamics
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.

4.2 Pharmacokinetics
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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major 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.

5.2 Shelf life

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

Shelf life after first opening the immediate packaging: Use immediately.Dispose of any unused product.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Low density polyethylene bottles of 250, 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:
20 bottles with 250 ml solution for infusion
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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Braun Melsungen AG.,

7 MARKETING AUTHORISATION NUMBER(S)

VPA10465/003/001

8. DATE OF FIRST AUTHORISATION

17 August 2012

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

13 March 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).