

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard-boxes containing low density polyethylene bottles 20 x 250 ml
Cardboard-boxes containing low density polyethylene bottles 10 x 500 ml
Cardboard-boxes containing low density polyethylene bottles 10 x 1000 ml
Cardboard-boxes containing plastic bags of 2 x 5000 ml

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. STATEMENT OF ACTIVE SUBSTANCES

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)

Electrolytes:

Na	130.49	mmol/l
K	5.37	mmol/l
Ca	1.84	mmol/l
Cl	111.70	mmol/l
Lactate	27.84	mmol/l

3. PACKAGE SIZE

20 x 250 ml
10 x 500 ml
10 x 1000 ml
2 x 5000 ml

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:

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

Cattle, horses, sheep, goats: Milk: zero hours.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Protect from light.

LDPE_bottle: Keep the bottle in the outer carton.

Plastic bag: Keep the plastic bag in the outer carton.

Do not refrigerate or freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot number.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Low density polyethylene bottle 250 ml
Low density polyethylene bottle 500 ml
Low density polyethylene bottle 1000 ml
Plastic bag of 5000 ml

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. STATEMENT OF ACTIVE

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)

Electrolytes:

Na	130.49	mmol/l
K	5.37	mmol/l
Ca	1.84	mmol/l
Cl	111.70	mmol/l
Lactate	27.84	mmol/l

3. TARGET SPECIES

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

4. ROUTES OF ADMINISTRATION

Intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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

Cattle, horses, sheep, goats: Milk: zero hours.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Protect from light.

LDPE bottle: Keep the bottle in the outer carton.

Plastic bag: Keep the plastic bag in the outer carton.

Do not refrigerate or freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

9. BATCH NUMBER

Lot number.:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

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. 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:

Water for injection, q.s.

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

Theoretical osmolarity 277 mOsm/l

Titration acidity < 1 mmol/l

pH 5.0 - 7.0

Clear, colourless, aqueous solution.

3. Target species

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

4. Indications for use

Indications for all target animal species:

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

5. Contraindications

Do not use in animals with:

- Alkalosis of any origin
- Oedema (hepatic, renal, or cardiac)
- Overhydration
- Hyperkalaemia, hypernatraemia, hyperlactataemia
- Hepatic insufficiency

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

6. Special warnings

Special warnings:

None.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Not applicable

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.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

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.

Special restrictions for use and special conditions for use:

Not applicable.

7. Adverse events

Undetermined frequency (cannot be estimated from the available data)	Cardiac disorder ¹
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¹Due to the calcium content, effect on the heart cannot be ruled out.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Do not use if container or closure is damaged.

For single use only.

Solutions containing visible solid particles should not be administered.

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/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/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.

9. Advice on correct administration

Slow infusion into a large blood vessel should be performed under conditions of strict asepsis. Do not inject intramuscularly.

The general precautions for the use of infusion solutions are applicable.

Use immediately after opening the immediate package.

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

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. Withdrawal periods

Dogs and cats: Not applicable.

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

Cattle, horses, sheep, goats: Milk: zero hours.

11. Special storage precautions

Keep out of the sight and reach of children.

Protect from light.

Keep the bottle and the plastic bag in the outer carton.

Do not refrigerate or freeze.

Use immediately after opening the package.

Dispose of any unused product.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and the outer package after EXP. The expiry date refers to the last day of that month.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Low density polyethylene bottles of 250, 500 and 1000 ml

Three-laminate plastic bag (polypropylene inner layer) of 5000 ml

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.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Manufacturer responsible for batch release:

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Carretera de Terrassa,121
08191 Rubi (Barcelona) – Spain

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