

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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.

B. Braun Vet Care Hartmann's Lactated Ringers Solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats (United Kingdom/Ireland)

B. Braun Vet Care Ringer Lactate Hartmann Solution pour perfusion pour bovins, chevaux, moutons, chèvres, porcins, chiens et chats (Belgium)

B. Braun Vet Care Hartmann Ringerlactaat oplossing voor infusie voor runderen, paarden, schapen, geiten, varkens, honden en katten (Netherlands)

Ringer Lattato Hartmann B. Braun Vet Care soluzione per infusione per bovini, cavalli, pecore, capre, porci, cani e gatti (Italy)

Lactato-RingerVet solución para perfusión para bovino, equino, ovino, caprino, porcino, perros y gatos (Spain)

Ringer-Lactat-Lösung nach Hartmann B. Braun Vet Care, Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Hunde und Katzen (Germany/Austria)

2. STATEMENT OF ACTIVE AND OTHER 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. PHARMACEUTICAL FORM

Free from bacterial endotoxins.

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

Solution for infusion.

4. PACKAGE SIZE

LDPE bottle: 10 x 500 ml, 10 x 1000 ml
Plastic bag: 2 x 5000 ml

5. TARGET SPECIES

Cattle, horse, sheep, goat, pig, dog and cat

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

For single use only.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening the immediate package

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet before use

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
34209 Melsungen
Germany

In Spain:
B. Braun VetCare SA,
08191 Rubí (Barcelona), Spain

In Italy:
Manufacturer responsible for batch release:
B. Braun Medical SA
08191 Rubi (Barcelona) - Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch no.:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

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.

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Ringer-Lactat-Lösung nach Hartmann B. Braun Vet Care, Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Hunde und Katzen (Germany/Austria)

2. STATEMENT OF ACTIVE AND OTHER 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. PHARMACEUTICAL FORM

Free from bacterial endotoxins

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

Solution for infusion

4. PACKAGE SIZE

LDPE bottle: 500 ml, 1000 ml
Plastic bag: 5000 ml

5. TARGET SPECIES

Cattle, horse, sheep, goat, pig, dog and cat

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening the immediate package.

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
34209 Melsungen
Germany

In Spain:
B. Braun VetCare SA,
08191 Rubí (Barcelona), Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch no.:

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder

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

In Spain:
B. Braun VetCare SA
Carretera de Terrassa, 121
08191 Rubí (Barcelona), Spain

Postal address:
34209 Melsungen
Germany

Manufacturer for batch release:

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

B. Braun Medical SA
Carretera de Terrassa, 121
08191 Rubí (Barcelona)
Spain

Postal address:
34209 Melsungen
Germany

2. 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.

B. Braun Vet Care Hartmann's Lactated Ringers Solution for infusion for cattle, horses, sheep, goats, pigs, dogs and cats (United Kingdom/Ireland)

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Ringer-Lactat-Lösung nach Hartmann B. Braun Vet Care, Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Hunde und Katzen (Germany/Austria)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

B. Braun Vet Care Hartmann's Lactated Ringers solution is a clear, colourless, aqueous solution and free from bacterial endotoxins.

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(s):

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	

4. INDICATION(S)

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

6. ADVERSE REACTIONS

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horse, sheep, goat, pig, dog and cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

Only for administration by a veterinarian.

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).

10. WITHDRAWAL PERIODS

Cattle, horses, sheep, goats and pigs:

Meat and offal: zero days.

Milk: zero hours.

11. SPECIAL STORAGE PRECAUTION

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 WARNINGS

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

User Warnings

Not applicable

Use during 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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL; IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XXXXXXXXXX

15. OTHER INFORMATION**Presentations**

Low density polyethylene bottles of 500 and 1000 ml

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

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.

For animal treatment only.

Legal category

To be supplied only on veterinary prescription

For Spain: To be administered only by a veterinary surgeon.