LABELLING AND PACKAGE LEAFLET

A. LABELLING

DRAFT-PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Ecoflac plus bottle 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
Solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 ml solution for infusion contain:

Active substances:

Sodium chloride	7.5 g

Excipients:

Water for injection to	100 ml

Electrolytes	
Na	1283 mmol/l
Cl	1283 mmol/l
Theoretical osmolarity:	2566 mOsm/l

3. PHARMACEUTICAL FORM

Solution for infusion.

Free from bacterial endotoxins

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

To be used in horses, cattle, sheep, goats, pigs, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horses, cattle, sheep, goats and pigs:
meat and offal: Zero days
milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Cloudy solutions or solutions containing visible solid particles should not be administered.
Do not use if container or closure is damaged. For single use only.
Do not reconnect partially used infusion bottles. Discard any unused contents.

10. EXPIRY DATE

Expiry date {month/year}

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.

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

Disposal: read package leaflet

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

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
Carl-Braun Strasse 1
34212 Melsungen
Hessen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 03551/4003

17. MANUFACTURER'S BATCH NUMBER

Batch no

DRAFT-PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Ecoflac plus bottles 1 x 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
Solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 ml solution for infusion contain:

Active substances:

Sodium chloride	7.5 g

Excipients:

Water for injection to	100 ml

Electrolytes	
Na	1283 mmol/l
Cl	1283 mmol/l
Theoretical osmolarity:	2566 mOsm/l

3. PHARMACEUTICAL FORM

Solution for infusion.

Free from bacterial endotoxins

4. PACKAGE SIZE

1 x 500 ml

5. TARGET SPECIES

To be used in horses, cattle, sheep, goats, pigs, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horses, cattle, sheep, goats and pigs:
meat and offal: Zero days
milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Cloudy solutions or solutions containing visible solid particles should not be administered.
Do not use if container or closure are damaged. For single use only.
Do not reconnect partially used infusion bottles. Discard any unused contents.

10. EXPIRY DATE

Expiry date {month/year}

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.

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

Disposal: read package leaflet

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To be supplied only on veterinary prescription.
In Spain only: To be administered only by a veterinary surgeon.

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B.Braun Melsungen AG,
Carl-Braun Strasse 1
34212 Melsungen
Hessen
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)

Vm 03551/4003

17. MANUFACTURER'S BATCH NUMBER

Batch no

DRAFT-PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Ecoflac plus bottles 10 x 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
Solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

100 ml solution for infusion contain:

Active substances:

Sodium chloride	7.5 g

Excipients:

Water for injection to	100 ml

Electrolytes	
Na	1283 mmol/l
Cl	1283 mmol/l
Theoretical osmolarity:	2566 mOsm/l

3. PHARMACEUTICAL FORM

Solution for infusion.

Free from bacterial endotoxins

4. PACKAGE SIZE

10 x 500 ml

5. TARGET SPECIES

To be used in horses, cattle, sheep, goats, pigs, dogs and cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horses, cattle, sheep, goats and pigs:
meat and offal: Zero days
milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Cloudy solutions or solutions containing visible solid particles should not be administered.
Do not use if container or closure are damaged. For single use only.
Do not reconnect partially used infusion bottles. Discard any unused contents.

10. EXPIRY DATE

Expiry date {month/year}

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.

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

Disposal: read package leaflet

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

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
Carl-Braun Strasse 1
34212 Melsungen
Hessen
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)

Vm 03551/4003

17. MANUFACTURER'S BATCH NUMBER

Batch no:

A. PACKAGE LEAFLET

PACKAGE LEAFLET:

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
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
postal address:
34209 Melsungen
Germany

Manufacturer:
B. Braun Medical SA
Carretera de Terassa, 121
08191 Rubí (Barcelona)
Spain

For the Spanish product:
Marketing Authorisation Holder:
B. Braun VetCare SA
Carretera de Terassa, 121
08191 Rubí (Barcelona)
Spain

Manufacturer:
B. Braun Medical SA
Carretera de Terassa, 121
08191 Rubí (Barcelona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml)
Solution for infusion for horses, cattle, sheep, goats, pigs, dogs and cats (UK/IE)

Hipertónico Salino 7.5 g/100 ml solución para perfusión para bovino, equino, ovino, caprino, porcino, perros y gatos (ES)

Hypertone Natriumchlorid-Lösung 7.5 g/100 ml B. Braun Vet Care
Infusionslösung für Pferde, Rinder, Schafe, Ziegen, Schweine, Hunde und Katzen (DE/AT)

B. Braun Vet Care hypertonique NaCl-Solution (7.5 g/100 ml)
Solution pour perfusion pour chevaux, bovins, moutons, chèvres, porcins, chiens et chats (FR/BE)

B. Braun Vet Care hypertonic NaCl-Oplossing (7.5 g/100 ml)
Oplossing voor infusie voor paarden, runderen, schapen, geiten, varkens, honden en katten (NL)

Sodio Cloruro 7,5 g/100 ml B. Braun Vet Care soluzione ipertonica per infusione per cavalli, bovini, pecore, capre, porci, cani e gatti (IT)

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

B. Braun Vet Care hypertonic NaCl-Solution (7.5 g/100 ml) is a clear, colourless aqueous solution.

100 ml solution for infusion contain:

Active substance:

Sodium chloride	7.5 g

Excipient(s):

Water for injection to	100 ml

Electrolytes	
Na	1283 mmol/l
Cl	1283 mmol/l
Theoretical osmolarity:	2566 mOsm/l

Free from bacterial endotoxins.

4. INDICATION(S)

Indications for all target animal species:
As adjunctive therapy in the treatment of emergency situations, like haemorrhagic, endotoxic, septic or hypovolaemic shock, when a rapid increase in the plasma circulation volume is required in order to restore or maintain vital organ functions.

5. CONTRAINDICATIONS

Do not use in animals with:

Hypertonic hyperhydration;
Renal insufficiency;
Severe electrolyte disturbances;
Uncontrolled haemorrhage;
Pulmonary oedema;
Retention of water and sodium chloride;
Cardiac insufficiency;
Hypertension;
Hypertonic dehydration.

6. ADVERSE REACTIONS

An excess of sodium may cause hypokalaemia, which may be aggravated by the existence of continued loss of potassium and hyperchloraemia.
Erroneous administration of hypertonic NaCl-Solution to dehydrated animals may increase the existing extracellular hypertonia, with aggravation of existing disorders, and may cause death.
Rapid infusion may cause oedema, principally pulmonary oedema, especially in case of concurrent cardiac or renal insufficiency. After rapid administration, hypotension, arrhythmias, haemolysis, haemoglobinuria, bronchoconstriction as well as hyperventilation may occur.
Administration into small peripheral veins may cause signs of pain.
Infusion of hypertonic sodium chloride may provoke diuresis with formation of hypertonic urine.

A risk of thrombosis should be considered.

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

7. TARGET SPECIES

Horses, cattle, sheep, goats, pigs, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Administration by intravenous route.

The recommended dosage is 3 to 5 ml/kg body weight which have to be administered over a period of maximum 15 minutes, without exceeding a rate of 1 ml/kg body weight/min. Administration of hypertonic sodium chloride should be followed by infusion of isotonic fluids over one or two hours in order to restore the hydration state of the interstitial space.

Under the control of a veterinarian the dosage should be adjusted to meet the specific evolving demands of the animal under treatment.

9. ADVICE ON CORRECT ADMINISTRATION

The solution should be administered slowly and at body temperature to avoid hypothermia.

Maintain aseptic precautions during administration.

Cloudy solutions or solutions containing visible solid particles should not be administered.

Do not use if container or closure are damaged. For single use only.
Do not reconnect partially used infusion bottles.

10. WITHDRAWAL PERIODS

Horses, cattle, 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 direct sunlight.
Do not use after the expiry date indicated on the label and the outer package.

12. SPECIAL WARNINGS

Special precautions for use in animals

Any existing haemorrhage should be stopped or controlled before treatment.

Hypertonic solutions must be administered solely by intravenous route.

Excessive administration of chloride may, due the electrolyte's interaction with the body's bicarbonate buffer system, exert an acidifying effect. Therefore, in clinical instances accompanied by acidosis and hyperchloraemia, special care has to be taken if this veterinary medicinal product is infused.

Sodium chloride administration may aggravate a pre-existing hypokalaemia.

In severe cases, the central venous pressure has to be monitored during administration.

Frequent monitoring of the water balance is recommended.

Adequate access to drinking water should be provided when using the product.

Rapid infusion of hypertonic NaCl can lead to myelinolysis in the brain in animals with chronic hyponatraemia.

Care should be taken to avoid the use of excessive doses (> 8 ml/kg body weight) and excessive dose rates (> 60 ml/kg body weight/h).

Animals treated with this veterinary medicinal product should be closely observed for possible deterioration of the clinical condition as a consequence of treatment.

Repeated infusion should only be performed after checking sodium concentration and acid-base status.

Use during pregnancy and lactation

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

Interaction with other medicinal products and other forms of interaction

Administer with care to animals that have had prolonged treatment with corticosteroids having a mineralocorticoid action.

Overdose

Overdose of hypertonic sodium chloride solution may lead to an increase in the extracellular volume (extracellular hyperhydration). Hyperhydration is manifest by agitation and hypersalivation: in these cases, it is appropriate to reduce the rate of infusion drastically or to stop the infusion.

Strict observation of the patient is necessary to safeguard the maintenance of correct diuresis and to avoid to cause cardiovascular overload and pulmonary or cerebral oedema.

Fluid output, plasma sodium concentration and blood pressure should be monitored. If hypernatraemia is present, it should be corrected slowly, using water orally if possible, or intravenous 0.9% sodium chloride solution, or for less severe hypernatraemia, an intravenous isotonic electrolyte solution with a low sodium chloride concentration.

An increase of serum osmolarity over 350 mOsm/l may produce cerebral dysfunction and coma.

If the solution is administered exclusively and in large doses, the chloride ions displace bicarbonate ions and induce an acidosis.

Overdose of the veterinary medicinal product can cause hypernatraemia.

Incompatibilities

Solutions containing sodium chloride are incompatible with Amphotericin B, since Amphotericin B precipitates in the presence of sodium chloride.
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

Dispose of waste material in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentations

Bottle with 500 ml of solution for infusion
10 bottles with 500 ml of solution for infusion

Not all pack sizes may be marketed.

For animal treatment only.

In Spain only:
To be supplied only on veterinary prescription.
To be administered only by a veterinary surgeon

Approved: 24 December 2019