LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polyethylene bottles of 100, 250, 500 and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care
solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

2. STATEMENT OF ACTIVE SUBSTANCES

100 ml contains:

Active substance:

Sodium chloride	0.9 g
Theoretical osmolarity	308 mOsm/l
pH	4.5 - 7

Electrolyte concentration:

Sodium	154 mmol/l
Chloride	154 mmol/l

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

20x100 ml
20x250 ml
10x500 ml
10x1000 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use. Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Use immediately after first opening, do not store.

11. SPECIAL STORAGE CONDITIONS

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

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 03551/4005

17. MANUFACTURER'S BATCH NUMBER

LOT

Blue box requirement:

UK only:
Vm: 03551/4005
POM-V
To be supplied only on veterinary prescription.

IE only:
VPA 10465/004/001
POM

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Polyethylene bottles of 100, 250, 500 and 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care
solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

2. STATEMENT OF ACTIVE SUBSTANCES

100 ml contains:

Active substance:

Sodium chloride	0.9 g
Theoretical osmolarity	308 mOsm/l
pH	4.5 - 7

Electrolyte concentration:

Sodium	154 mmol/l
Chloride	154 mmol/l

3. PHARMACEUTICAL FORM

Solution for infusion

4. PACKAGE SIZE

100 ml
250 ml
500 ml
1000 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intravenous use/IV use. Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after first opening, do not store.

11. SPECIAL STORAGE CONDITIONS

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

Dispose of waste material in accordance with local requirements. 250 und 500 ml
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. 1000 ml

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG
34209 Melsungen, Germany

16. MARKETING AUTHORISATION NUMBER

Vm 03551/4005

17. MANUFACTURER'S BATCH NUMBER

LOT

Blue box requirement:

UK only:
Vm: 03551/4005
POM-V
To be supplied only on veterinary prescription.

IE only:
VPA 10465/004/001
POM

PACKAGE LEAFLET

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care 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 Postal address:
34212 Melsungen, Germany 34209 Melsungen, Germany

Manufacturer responsible for batch release:
B. Braun Melsungen AG
Carl-Braun Straße 1 Postal address:
34212 Melsungen, Germany 34209 Melsungen, Germany

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

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

Sodium Chloride 0.9 g/100 ml B. Braun Vet Care solution for infusion is a clear, colourless aqueous solution.

Each 100 ml of solution for infusion contains:

Sodium chloride 0.9 g

Water for injections

4. INDICATION(S)

It is used in all the animal target species for:

- States of dehydration and hypovolaemia
- Deficiency of sodium (hyponatraemia) and chloride (hypochloraemia)
- Hypochloraemic alkalosis management

- Vehicle solution for compatible drugs
- External use for wound irrigation and moistening of compresses

5. CONTRAINDICATIONS

Do not use in animals with: salt and water retention, syndrome of ascites and oedema, acidosis, hypertonic dehydration, hypernatraemia, hyperchloraemia.

6. ADVERSE REACTIONS

Intravenous infusion carries a risk of thrombosis.
Please see section 12. for symptoms of overdose.

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 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

Intravenous use. Topical use for wound irrigation and moistening of compresses.

Maximum daily dosage:
The dosage must be adjusted to the specific case, depending on the requirements of the state of the animal and under control of a veterinarian.

Maximum infusion rate:
Generally, it is recommended that the infusion rate should be adapted to the existing fluid deficit. Higher infusion rates are required in case of hypovolaemic shock (dog: up to 100 ml/kg b.w./h; cat: up to 60 ml/kg b.w./h; horse, cattle, neonate calf: 50 to 80 ml/kg b.w./h). Although no specific maximum infusion rates for small ruminants and pigs are available in the scientific literature, there is evidence that those applicable to cattle can be used safely. In case of long-term intravenous infusion therapy 5 to 10 ml/kg b.w./h should normally not be exceeded. However, in some cases, it may be necessary to increase the infusion rates above these levels.
During rapid intravenous fluid administration the animals should be monitored for signs of fluid overload (principally pulmonary oedema).

General guidelines on fluid intake:
The dosage of infusion solutions should always be adapted according to the existing fluid requirement of the animal. The total deficit replacement volume results from the amount of maintenance volume plus the amount of deficit volume. The ***maintenance volume*** corresponds to the normal fluid losses due to perspiration, sweating, urine and faeces minus the amount of water which is generated in the intermediary

metabolism. Under normal conditions there are the following recommendations for maintenance volume in adult animals:

Body weight (kg)	**Maintenance volume (ml/kg b.w./d)**
< 5	80 to 120
5 to 20	50 to 80
20 to 100	30 to 50
> 100	10 to 30

An ***existing fluid deficit*** due to fever, diarrhoea, haemorrhage, vomiting or an absolute and relative intravasal volume deficit must be replaced by an additional fluid intake, depending on the dehydration degree:

Dehydration degree (% of b.w.)	**Deficit volume (mL/kg b.w./d)**
Slight (4 to 6%)	40 to 60
Moderate (6 to 8%)	60 to 80
Severe (> 8%)	> 80 (to 120)

9. ADVICE ON CORRECT ADMINISTRATION

The dosage and duration of treatment must be adjusted according to the specific fluid and electrolyte requirements under control of a veterinarian to prevent any possible side effects due to overdose.
High infusion rates should be avoided in cases of chronic hyponatraemia All the relevant aseptic precautions must be maintained during intravenous or topical administration. Do not use unless the solution is clear, free from visible particles, and the container is undamaged.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. Use immediately after opening the package. Dispose of any unused product. This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
Use with caution in animals with cardiac or renal impairment as sodium overload may occur. The maximum infusion rate should be decreased in the presence of cardiac, renal and pulmonary disease.
Use with caution post surgery/trauma as sodium excretion may be impaired. Use with caution in animals with hypokalaemia. Serum electrolyte levels, water and acid-base balance and the clinical condition of the animal should be closely monitored during the treatment in order to prevent overdose, particularly in cases of renal or metabolic changes.
This product should not be used for longer than is necessary to correct and sustain circulating volume. Inappropriate/excessive use may worsen or create a metabolic acidosis.
The solution should be warmed to approximately 37ºC prior to the administration of large volumes, or if the administration rate is high, in order to avoid hypothermia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Pregnancy and lactation:
Administer only after risk/ benefit evaluation.

Interaction with other medicinal products and other forms of interaction:
Caution should be taken if the infusion is administered concomitantly with drugs known to cause sodium retention (e.g. corticosteroids). Concurrent administration of colloids will require a reduction in dose.

Overdose (symptoms, emergency procedures, antidotes):
Overdose may lead to hypernatraemia, hyperchloraemia, hypokalaemia, cardiac decompensation hyperhydration and metabolic acidosis.

Clinical signs:
Restlessness, hypersalivation, shivering, tachycardia, serous nasal discharge, tachypnoea, moist rales, coughing, protusion of the eye from the orbit, widespread oedema, vomiting and diarrhoea.

Treatment:
In these cases, the rate of infusion should be drastically reduced or even discontinued.
Close monitoring of the animal is needed. Cardiovascular overload and pulmonary or cerebral oedema can be avoided by observing the maintenance of a proper diuresis. In case oedema occurs, the rate of infusion should be reduced or the infusion should be stopped. Supportive measures should be applied.

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 MATERIALS, 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

15. OTHER INFORMATION

Pharmacological properties
Pharmacotherapeutic group: Electrolyte solutions
ATCvet code: QB05BB01

Pharmacodynamic properties
Sodium Chloride 0.9 g/100 ml is an isotonic solution containing sodium and chloride with an osmolarity of 308 mOsml/l. Sodium is the major cation of the extracellular space and regulates the size of this space together with other anions.

The sodium content and the fluid homeostasis of the body are closely related to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body. An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolarity. A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space.

Pharmacokinetic particulars
Due to the i.v. application, the bioavailability of Sodium Chloride 0.9 g/100 ml is 100%.
Sodium and chloride are normal body constituents and their homeostasis is maintained by the kidneys. The sodium level in Sodium Chloride 0.9 g/100 ml is similar to physiological serum sodium level. The kidneys are the major regulator of the sodium and water balance. In co-operation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) the kidneys are primarily responsible for the maintenance of a constant volume of the extracellular space and regulation of its fluid composition. Chloride is exchanged for hydrogen carbonate in the tubule system. Thus, it is involved in the regulation of the acid-base balance.

Presentations
Boxes containing polyethylene containers with:
- 20 polyethylene containers of 100 ml
- 20 polyethylene containers of 250 ml
- 10 polyethylene containers of 500 ml
- 10 polyethylene containers of 1000 ml

Not all pack sizes may be marketed.

For animal treatment only.
To be supplied only on veterinary prescription. To be administered only by a veterinary surgeon.

UK only:
Vm: 03551/4005
POM-V
To be supplied only on veterinary prescription.

IE only:
VPA 10465/004/001
POM
Prescription Only Medicine

Approved: 07 August 2018