

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sterofundin ISO B. Braun Vet Care

Solution for infusion for cattle, horse, sheep, goat, pig, dog and cat

Sterofundin ISO B. Braun Vet Care

Infusionslösung für Rinder, Pferde, Schafe, Ziegen, Schweine, Hunde und Katzen (AT/DE)

Isofundin solución para perfusión para bovino, caballos, ovino, caprino, porcino, perros y gatos (ES)

Isofundin solução para perfusão para bovinos, equinos, ovinos, caprinos, suínos, cães e gatos (PT)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

1 000 ml of solution for infusion contains

Sodium chloride	6.80 g
Potassium chloride	0.30 g
Magnesium chloride hexahydrate	0.20 g
Calcium chloride dihydrate	0.37 g
Sodium acetate trihydrate	3.27 g
L-Malic acid (E296)	0.67 g

Electrolyte concentrations:

Sodium	145.0 mmol/l
Potassium	4.0 mmol/l
Magnesium	1.0 mmol/l
Calcium	2.5 mmol/l
Chloride	127.0 mmol/l
Acetate	24.0 mmol/l
Malate	5.0 mmol/l

Excipients:

Qualitative composition of excipients and other constituents
Water for injections
Sodium hydroxide (for pH adjustment)

Solution for infusion

Clear, colourless aqueous solution

Theoretical osmolarity 309 mOsm/l

pH 5.1 – 5.9

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Dog and cat: Correction of hypotonic and isotonic dehydration, for fluid and electrolyte replacement under the conditions of undisturbed acid-base balance or mild acidosis.

Cattle, horse, sheep, goat and pig: Correction of hypotonic and isotonic dehydration and for fluid and electrolyte replacement under the conditions of undisturbed acid-base balance.

All target species: Short term intravascular volume replacement.

3.3 Contraindications

Do not use in:

Metabolic alkalosis

Oedema, associated with decompensated heart failure and renal/hepatic insufficiency

Severe renal insufficiency with oliguria or anuria

Hyperkalaemia, Hyponatremia

Hypertonic dehydration

Addison's disease

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.

Serum electrolyte status should be monitored in case of electrolyte imbalances, such as hypertonic or hypotonic dehydration, or a single increase of one electrolyte (e.g. hyperchloremia). In addition, the water balance (hydration) and acid base balance should be monitored during the administration of the solution.

Use with caution in congestive heart failure, renal insufficiency and in animals treated with corticoids and their derivatives.

Due to the potassium content of this solution it should be used prudently in severe renal impairment.

Due to the pH of the veterinary medicinal product it should not be administered subcutaneously.

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)	effect on the heart ¹ application site pain, application site reaction, venous irritation, venous phlebitis, thrombosis, extravasation hypersensitivity reaction (urticaria) ²
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¹Due to the calcium content, risk increases if the solution is administered too quickly.

²Occasional, has been reported in connection with intravenous administration of magnesium salts.

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 the national competent authority via the national reporting system. See section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according 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.

General guidance for fluid intake:

The volume and rate of infusion depends on the clinical condition, existing hydration deficits of the animal, maintenance needs and continuing losses and should be determined under the supervision of the responsible veterinarian for specific case.

Maintenance requirements for adult animals

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

Body weight (kg)	Maintenance volume ml/kg body weight/day
< 5	120-80
5-20	80-50
20-100	50-30
> 100	30-10

In cats:

1-8	80-50
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Maintenance requirements for small ruminants

Maintenance fluid requirements for small ruminants can be estimated using the following general guidelines:

- Adults: 50 ml/kg body weight/day
- Neonates: 70 to 80 ml/kg body weight/day

Estimation of dehydration grade:

Degree of dehydration (% kg body weight)	Volume deficit (ml/kg body weight/day)
Slight (4 – 6%)	40-60
Moderate (6 – 8%)	60-80
Severe (>8%)	>80 (-120)

The degree of dehydration can also be calculated as follows:

Degree of dehydration [%] x kg body weight x 10 = ml of volume substitution

Infusion rate:

It is generally recommended to adjust the infusion rate according to fluid deficiency. Half of the patient's calculated fluid deficit should be replaced within 6 hours, three quarters within 24 hours. The complete deficit should be replaced within 48 hours.

In general, 5 to 10 ml/kg body weight/h should not be exceeded for long-term intravenous infusion therapy.

Maximum infusion rate:

High infusion rates should only be used for resuscitation of animals in shock, only for a short period of time (20 to 30 minutes), and in the absence of pulmonary, renal or cardiac dysfunction.

The maximum infusion rate for the target species is provided in the following table:

Target species	Rate of fluid administered over a period of 10-15 minutes
Calf	should not exceed 80 ml/kg/h
Cattle	40 ml/kg/h
Horse	20 to 45 ml/kg/h
Dog	80-90 ml/kg/h
Cat	45-60 ml/kg/h

For small ruminants and pigs the maximum infusion rate should be individually calculated.

Clinical response of the animal rather than equations should be used to establish fluid therapy. In some cases increasing infusion rates above these values may be required.

Animals should be monitored closely for signs of hyperhydration (mainly pulmonary oedema) and the rapid administration of fluids should be discontinued when the patient is improving.

Fluid therapy and maximum infusion rates in paediatric animals should be adapted to the individual requirements established by the treating veterinarian.

Intravenous fluids should be warmed up to body temperature prior to administration.

Maintain aseptic precautions throughout administration.

Do not use if container or closure is damaged.

For single use only.

Solutions containing visible solid particles and/or showing discoloration 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.

Too large volumes or too rapid infusion rates of the veterinary medicinal product may lead to electrolyte and acid-base imbalances. Fluid and sodium overload, hyperkalemia, hypermagnesaemia, acidification of the blood due to overdose of chloride salts, metabolic alkalosis as a result of overdose of acetate and malate, and hypercalcemia and associated clinical signs may occur.

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 period

Cattle, horse, sheep, goat, pig:

Meat and offal: zero days

Cattle, horse, sheep, goat:

Milk: zero hours

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

I.V. Solutions affecting the electrolyte balance/electrolytes
QB05BB01.

4.2 Pharmacodynamics

The veterinary medicinal product is administered to prevent dehydration and to correct acid-base, fluid and electrolyte abnormalities in different clinical conditions. The electrolytes Na^+ , K^+ , Ca^{2+} , Mg^{2+} , are indispensable for the maintenance and correction of fluid and electrolyte homeostasis while the anion pattern represents a balanced combination of chloride, acetate, and malate which counteracts metabolic acidosis. All substrates are occurring during normal physiological metabolism.

4.3 Pharmacokinetics

Absorption and distribution

Due to intravenous administration the bioavailability of the active substances is 100%. The electrolytes are transferred to their respective electrolyte pools in the body. Sodium and chloride mainly distribute in the extracellular space, whereas the preferential distribution of potassium, magnesium and calcium is intracellular.

Biotransformation

Electrolytes are not metabolised in the strict sense. Malate and acetate are oxidised via the Krebs Cycle to carbon dioxide and water.

Elimination

The kidneys are the main route of excretion for sodium, potassium, magnesium, and chloride but small amounts are lost via the skin and intestinal tract.

Calcium is excreted in approximately equal amounts in urine and endogenous intestinal secretion.

Acetate and malate excretion in urine rises during the infusion. However, their metabolism by body tissues is so rapid that only a small fraction appears in urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

This veterinary medicinal product is incompatible with tetracycline and amphotericin B, because of the risk of forming chelate complexes with Ca^{2+} .

Mixing this veterinary medicinal product with solutions containing phosphates, carbonates, sulphates or tartrates may lead to precipitation.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Do not administer together with blood or through infusion sets that have been used or may be used for administration of blood, since the possibility of developing agglutination and hemolysis exists.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale (polyethylene bottles): 3 years

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

5.3 Special precautions for storage

Do not refrigerate or freeze.

5.4 Nature and composition of immediate packaging

Low density polyethylene bottles of 250, 500 and 1000 ml of capacity.
The additional closure cap on top of the sealed polyethylene container is made from high density polyethylene. Between the container and the closure cap an elastomeric latex free disk is placed.

Pack sizes:

Cardboard boxes containing:

10 x 250 ml

10 x 500 ml

10 x 1000 ml

Not all pack sizes may be marketed.

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

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.

Medicines should not be disposed via wastewater.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

B. Braun Melsungen AG

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}><{DD month YYYY}>.

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

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

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>).