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Directions for Use

B. Braun Melsungen AG · 34209 Melsungen, Germany

Sterofundin ISO

solution for infusion

Composition
1000 ml of solution contain

Active substances:	
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	0.67 g
Electrolyte concentrations:	*mmol/l*
Sodium	145.0
Potassium	4.0
Magnesium	1.0
Calcium	2.5
Chloride	127.0
Acetate	24.0
Malate	5.0

Excipients:
Water for injections
Sodium hydroxide

Pharmaceutical form
Solution for infusion

Pharmaco-therapeutic group
Solutions affecting the electrolyte balance, electrolytes; ATC code: B05BB01

Indications
Replacement of extracellular fluid losses in the case of isotonic dehydration, where acidosis is present or imminent.

Contraindications
- Hypervolaemia
- Severe congestive cardiac failure
- Renal failure with oliguria or anuria
- Severe general oedema
- Hyperkalaemia
- Hypercalcaemia
- Metabolic alkalosis

Special warnings and precautions for use
High volume infusion must be used under specific monitoring in patients with mild to moderate cardiac or pulmonary failure (for more severe conditions: see section "Contraindications").

Solutions containing sodium chloride should be administered with caution to patients with:
- mild to moderate cardiac insufficiency, peripheral or pulmonary oedema or extracellular hyperhydration (for more severe conditions: see section "Contraindications"),
- hypernatraemia, hyperchloraemia, hypertonic dehydration, hypertension, impaired renal function, present or imminent eclampsia, aldosteronism or other conditions or treatment (e. g. corticoids/steroids) associated with sodium retention (see also section "Interactions").

Solutions containing potassium salts should be administered with caution to patients with cardiac disease, or conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns.

Because of the presence of calcium:
- Care should be taken to prevent extravasation during intravenous infusion
- The solution should be given cautiously to patients with impaired renal function or diseases associated with elevated vitamin D concentrations such as sarcoidosis.
- In case of concomitant blood transfusion, the solution must not be administered via the same infusion set

Solutions containing metabolizable anions should be administered cautiously to patients with respiratory impairment.
Monitoring of the serum electrolytes, fluid balance, and pH is necessary.
During long-term parenteral treatment, a convenient nutritive supply must be given to the patient.
Vitamin D may induce hypercalcaemia.

Pregnancy and lactation
There are no data from the use of Sterofundin ISO in pregnant and lactating women. In the intended indication no risks have to be expected, when volume, electrolyte and acid/base levels are carefully monitored.
Sterofundin ISO should be used with caution in toxaemia of pregnancy.

Interactions
Sodium, potassium, calcium, and magnesium are present in Sterofundin ISO in the same concentrations as in plasma. Hence, the administration of Sterofundin ISO in accordance with the recommended indications and contraindications does not increase the plasma concentrations of said electrolytes. In case there is a rise of any electrolyte's concentration due to other reasons the following interactions should be considered.

Related to sodium:
Corticoids/steroids and carbenoxolone may be associated with the retention of sodium and water (with oedema and hypertension).

Related to potassium:
- Suxamethonium,
- Potassium-sparing diuretics (amiloride, spironolactone, triamterene, alone or in association),
- Tacrolimus, cyclosporine

may increase the concentration of potassium in the plasma and lead to potentially fatal hyperkalaemia notably in case of renal failure increasing the hyperkalaemic effect.

Related to calcium:
Digitalis glycosides (digitalis cardiotonics) may undergo enhancement of their effects during hypercalcaemia and lead to serious or fatal cardiac arrhythmia. Admixture of the medicinal product with medications containing carbonates, phosphates, sulphates or tartrates may lead to precipitation.

Dosage
Adults, the elderly, adolescents and children:
The dosage depends on the age, weight, clinical and biological conditions of the patient and concomitant therapy.

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Recommended dosage:
The recommended dosage is:
- for adults, the elderly and adolescents : 500 ml to 3 litres /24h, corresponding to 1 to 6 mmol sodium / kg / 24 h and 0.03 to 0.17 mmol potassium / kg / 24 h.
- for babies and children : 20 ml to 100 ml / kg / 24 h, corresponding to 3 to 14 mmol sodium / kg / 24 h and 0.08 to 0.40 mmol potassium / kg / 24 h.

Administration rate:
The maximum infusion rate depends on the needs of the patient in fluid replacement and electrolytes, his weight, clinical condition, and biological status.
In *paediatric patients* the infusion rate is 5 ml/kg/h on average but the value varies with age: 6-8 ml/kg/h for infants, 4-6 ml/kg/h for toddlers, and 2-4 ml/kg/h for schoolchildren.

Note:
- infants and toddlers: age ranges from about 28 days to 23 months (a toddler is an infant who can walk)
- children and schoolchildren: age ranges from about 2 years to 11 years.

Method of administration
For intravenous use as infusion only.
The solution has a pH of 5.1 – 5.9 and a theoretical osmolarity of 309 mosm/l.
Sterofundin ISO can be infused into peripheral veins.
If administration is by rapid infusion under pressure, all air must be withdrawn from the plastic container and infusion set prior to infusion, as otherwise there is a risk of producing air embolism during infusion.

Monitoring
Fluid balance, plasma electrolyte concentrations and pH must be monitored during administration.
Sterofundin ISO may be administered as long as there is an indication for fluid replacement.

Overdose
Overuse or too fast administration may lead to water and sodium overload with a risk of oedema, particularly when there is a defective renal sodium excretion. In this case extra renal dialysis may be necessary.
Excessive administration of potassium may lead to the development of hyperkalaemia, especially in patients with renal impairment. Symptoms include paresthesia of the extremities, muscle weakness, paralysis, cardiac arrhythmias, heart block, cardiac arrest, and mental confusion. Treatment of hyperkalaemia involves the administration of calcium, insulin (with glucose) sodium bicarbonate, exchange resins or dialysis.
Excessive parenteral administration of magnesium salts leads to the development of hypermagnesaemia, important signs of which are loss of deep tendon reflexes and respiratory depression, both due to neuromuscular blockade. Other symptoms of hypermagnesaemia may include nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, muscle weakness, bradycardia, coma, and cardiac arrest.
Excessive administration of chloride salts may cause a loss of bicarbonate with an acidifying effect.
Excessive administration of compounds, such as acetate and malate, which are metabolised to from the bicarbonate anion may lead to metabolic alkalosis, especially in patients with impaired renal function. Symptoms may include mood changes, tiredness, shortness of breath, muscle weakness, and irregular heartbeat. Patients with additional hypocalcaemia may develop muscle hypertonicity, twitching, and tetany. Treatment of metabolic alkalosis associated with an increase in bicarbonate consists mainly of appropriate correction of fluid and electrolyte balance.
Excessive administration of calcium salts may lead to hypercalcaemia. Symptoms of hypercalcaemia may include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, renal calculi, and, in severe cases, cardiac arrhythmias and coma. Too rapid intravenous injection of calcium salts may also lead to many of the symptoms of hypercalcaemia as well as to a chalky taste, hot flushes, and peripheral vasodilation. Mild asymptomatic hypercalcaemia will usually resolve on stopping administration of calcium and other contributory drugs such as vitamin D. If hypercalcaemia is severe, urgent treatment (such as loop diuretics, haemodialysis, calcitonin, bisphosphonates, trisodium edetate) is required.
When overdose is related to medications added to the solution infused, the signs and symptoms of overinfusion will be related to the nature of the additive being used. In the event of accidental overinfusion, treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the drug administered. The relevant symptomatic and supportive measures should be provided as necessary.

Undesirable effects
Signs of overdose may occur, see section "Overdose" above.
Hypersensitivity reactions characterized by urticaria have been occasionally described after the intravenous administration of magnesium salts.
Although oral magnesium salts stimulate peristalsis, paralytic ileus has been rarely reported after intravenous infusion of magnesium sulphate.
Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis extending from the site of injection and extravasation. Adverse reactions may be associated to the medications added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects.

Note:
Patients should inform their doctor or pharmacist if they notice any side effect not mentioned in this leaflet.

Expiry date
The product must not be used beyond the expiry date stated on the labelling.

Instructions for storage / use / handling
Do not store above 30°C. Do not refrigerate or freeze.
Single use only. Unused solution should be discarded.
Only clear solutions practically free from particles should be used.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
If using plastic bags, surrounding bag must only be removed immediately before use.
For further information please refer to section "Dosage".

Presentation
Polyethylene bottle (Ecoflac plus) 250 ml, 500 ml, 1000 ml. Polypropylene bag (Ecobag) 500 ml

Date of last revision: 08.2009

Product Registration Holder:
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