85/12622072/1215

Directions for Use
Read carefully!

Sterofundin ISO solution for infusion

Composition

1000 ml Sterofundin ISO solution for infusion contain:

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 (for pH adjustment)

Pharmaceutical form

Solution for infusion.
A clear, colourless aqueous solution

pH: 5.1 – 5.9
Theoretical osmolarity: 309 mosm/l.

Pharmacodynamic properties

Pharmacotherapeutic group: Solutions effecting the electrolyte balance, electrolytes
ATC code: B05BB01

This medicinal product is an isotonic electrolyte solution with electrolyte concentrations adapted to plasma electrolyte concentrations. It is used to correct extracellular fluid losses (i.e. losses of water and electrolytes in proportional amounts). The supply of the solution is aimed to restore as well as maintain normal osmotic conditions in the extracellular and intracellular space.

The anion pattern represents a balanced combination of chloride, acetate, and malate which counteracts metabolic acidosis.

Pharmacokinetic properties

Since the ingredients of Sterofundin ISO are infused intravenously their bioavailability is 100 %.

Sodium and chloride mainly distribute in the extracellular space, whereas the preferential distribution of potassium, magnesium and calcium is intracellular. 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.

During the infusion of acetate and malate, their plasma levels rise and appear to reach a steady state. Following termination of the infusion, the acetate and malate concentrations rapidly diminish. 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.

Therapeutic indications

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

Posology and method of administration

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

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 school children.

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

Method of administration
For intravenous use as infusion only.
Sterofundin ISO can be infused into peripheral veins (see section "Pharmaceutical form" for pH and theoretical osmolarity).

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.

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.

Contraindications

Sterofundin ISO must not be administered in the following situations:
- Hypervolaemia
- Severe congestive cardiac failure
- Renal failure with oliguria or anuria
- Severe general oedema
- Hyperkalaemia
- Hypercalcaemia
- Metabolic alkalosis

Special warning 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 with other medicinal products and other forms of interaction").

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.

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Interaction with other medicinal products and other forms of interaction

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.

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.

Effects on ability to drive and use machines

Sterofundin ISO has no influence on the ability to drive and use machines.

Undesirable effects

Signs of overdose may occur, see section "Overdose".

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.

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.

Incompatibilities

Admixture of the medicinal product with medications containing carbonates, phosphates, sulphates or tartrates may lead to precipitation.

Shelf life

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

Special precautions for storage

The product should not be stored above the temperature stated on the label. Do not refrigerate or freeze.

Presentation

500 ml, 1000 ml

Instructions for use and handling

Only for intravenous use.
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 "Posology and method of administration".

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