NAME OF THE MEDICINAL PRODUCT

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 with known effect:
1000 ml Sterofundin ISO solution contain 0.2 g Sodium hydroxide (0.115 g Sodium).

Excipients: Water for injection, sodium hydroxide (for pH adjustment).

THERAPEUTIC INDICATIONS

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

CONTRAINDICATIONS

Sterofundin ISO must not be administered in the following conditions:

Hypervolemia; severe congestive cardiac failure; renal failure with oliguria or anuria; severe general edema; hyperkalemia; hypercalcemia; metabolic alkalosis.

Effective

UNDESIRABLE EFFECTS

Signs of overdose may occur.

Undesirable effects are listed according to their frequency terms used in this section:

Rare: (≥ 1/10 000 to < 1/1000)
Not known: (cannot be estimated from the available data)

Immune system disorders
Not known: Hypersensitivity reactions characterised by urticaria have been occasionally described after the intravenous administration of magnesium salts.

Gastrointestinal disorders
Although oral magnesium salts stimulate peristalsis, paralytic ileus has been rarely reported after intravenous infusion of magnesium sulphate.

General disorders and administration site conditions
Adverse reactions may be associated with 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.

WARNINGS

Keep out of the sight and reach of children. Do not reconnect partially used containers. Discard unused contents. Do not use if container or closure is damaged. Solutions containing visible solid particles should not be administered. For single use only. (Expel all air before pressure infusion.)[1]

[1] For polyethylene plastic bottles only

NOTE

Prescription only
Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product information and availability.

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Effective