

Package leaflet: Information for the user

Sterofundin ISO solution for infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. this includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sterofundin ISO is and what it is used for
2. What you need to know before you receive Sterofundin ISO
3. How to use Sterofundin ISO
4. Possible side effects
5. How to store Sterofundin ISO
6. Contents of the pack and other information

1. What Sterofundin ISO is and what it is used for

Sterofundin ISO is a solution for infusion into a vein.

This solution replaces fluid that has been lost from the circulation. It can be used in conditions where your blood may become or has become slightly acidic.

2. What you need to know before you receive Sterofundin ISO

You will not be given Sterofundin ISO

if you have

- too much fluid in the circulation,
- severe heart disease with shortness of breath and swelling of the feet or the legs,
- severe kidney disease and you are unable or almost unable to pass urine,
- swelling of your body tissues due to fluid accumulation,
- high levels of potassium or calcium in your blood,
- or if your blood is too alkaline.

Warnings and precautions

Talk to your doctor or pharmacist before using Sterofundin ISO.

Special care will be taken with Sterofundin ISO Solution for infusion, if you have

- any disease that makes it necessary to reduce your salt intake, such as mild or moderately impaired heart function, tissue swelling or fluid accumulation in the lungs

- sarcoidosis (a chronic immune system disorder involving the lymph nodes and the connective tissue)
- mildly or moderately increased blood pressure
- acute water deficit e.g. following extensive tissue destruction as occurs with severe burns or due to impaired function of the adrenal glands
- high levels of sodium or chloride in your blood
- eclampsia (a complication occurring during pregnancy)
- mild or moderate impairment of your kidney function
- breathing problems
- any disease or if you receive any medicine that may lead to reduced excretion of sodium.

If any of the above mentioned applies to you, your doctor will decide very carefully whether this solution is suitable for you.

Your body fluid level and the salt concentrations in your blood will be controlled while you receive Sterofundin ISO to make sure that they are normal.

Other medicines and Sterofundin ISO

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is particularly important that your doctor knows if you take, use or receive:

- Drugs that make your body retain sodium and water such as
 - steroid hormones or
 - carbenoxolone
 If these are used together with Sterofundin ISO your body water level and your blood sodium level may increase, leading to swelling and increased blood pressure.
- Drugs with an influence on your blood potassium level such as
 - suxamethonium
 - some diuretics (water tablets) that lower your potassium excretion, e.g. amiloride, spironolactone, triamterene
 - tacrolimus, ciclosporin (drugs used e.g. to suppress the rejection of transplanted organs)
 If these are used together with Sterofundin ISO your blood potassium level could rise, which may lead to adverse effects on your heart function. This is more likely to happen if you suffer from impaired kidney function.
- *Digitalis* preparations (i.e. digoxin), which are used to treat heart weakness
 The effect of these will become stronger when the blood calcium level rises and adverse effects such as irregular heartbeat may occur. Therefore your doctor will need to re-adjust your digoxin dose.
- Vitamin D; this may lead to an increased blood calcium level.

Your doctor will know about the adverse effects that may be brought about by the combination of Sterofundin ISO and the aforementioned drugs. He will take care that the infusion you receive is dosed correctly.

Some drugs do not mix with Sterofundin ISO. Doctors only add drugs to Sterofundin ISO if they are sure they are safe to mix.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide whether this solution is suitable for you when you are pregnant.

This medicine will be used with caution in so-called toxæmia of pregnancy, a special complication that may occur during pregnancy.

Driving and using machines

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

Sterofundin ISO contains sodium

If you are on a controlled sodium diet, please note that this medicinal product contains 145 mmol sodium per 1000 ml.

3. How to use Sterofundin ISO

Route of administration

This medicine is given into a vein by a drip.

Dosage

Your doctor will determine the amount of solution you need.

In adults, elderly patients and adolescents this may be 500 millilitres – 3 litres per day. The daily dose for babies and children may be between 20 – 100 millilitres per kg body weight per day.

Rate of administration

Your doctor will also determine how fast the solution will be infused, depending on your body weight and your condition.

Duration of treatment

Your doctor will determine how long you will receive this solution.

While you receive the infusion, your fluid and salt levels and your blood acid-base balance will be controlled.

If you receive more Sterofundin ISO than you should

As your dose is controlled by a doctor or nurse, it is unlikely that you will be given too much of this solution.

However, if accidentally you did receive too much or the solution has run in too fast, you might get symptoms such as

- increase of skin tension
- congestion in veins and swelling
- accumulation of fluid in the lungs
- shortness of breath

- abnormalities in the water and salt composition of body fluids.

Excessively high blood levels of one the individual components of Sterofundin ISO may be associated with specific symptoms which your doctor will pay attention to.

In cases of overdose the infusion is stopped instantly and appropriate corrective therapy is started.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects may be caused by the administration technique. These may include feverish reactions, infection at the site of injection, local pain or reaction, vein irritation, blood clots in veins or inflammation of veins extending from the site of injection.

Allergic reactions to infused magnesium salts, presenting as rash, have been reported occasionally. The frequency of these reactions cannot be estimated from the available data.

Bowel paralysis has rarely been reported after infusion of magnesium sulphate. This may affect up to 1 in 1,000 people.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly at:

<http://www.medicinesauthority.gov.mt/adrportal>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sterofundin ISO

Keep this medicine out of the sight and reach of children.

Glass bottles and Polyethylene plastic bottles: Do not refrigerate or freeze.

Plastic bags: Do not store above 25°C. Do not refrigerate or freeze.

The medicinal product will not be used if there are particles in the solution or the solution is cloudy or discoloured. The product will not be used if the container is leaking or otherwise damaged. This product is for single-use only, partially used containers will not be reconnected.

Do not use this medicine after the expiry date which is stated on the label or the carton after EXP.

6. Contents of the pack and other information

What Sterofundin ISO contains

- **The active substances in Sterofundin ISO solution for infusion are:**

Per 1000 ml this medicine contains:

Sodium chloride	6.8 g
Potassium chloride	0.3 g
Magnesium chloride hexahydrate	0.2 g
Calcium chloride dihydrate	0.37 g
Sodium acetate trihydrate	3.27 g
Malic acid	0.67 g

- **The other ingredients are**

Water for injections, Sodium Hydroxide (for pH adjustment)

What Sterofundin ISO looks like and contents of the pack

Sterofundin ISO is a solution for infusion (for administration by a vein drip). It is a clear colourless solution.

It comes in

- Plastic bottles containing 250 ml, 500 ml or, 1000ml, available in packs of 1 or 10 bottles
- Plastic bags containing 250 ml, 500 ml or, 1000ml, available in packs of 1 or 20 bags (250 ml and 500 ml) or of 1 or 10 bags (1000 ml)
- Glass bottles containing 250 ml, 500 ml or, 1000ml, available in packs of 1 or 10 bottles (250 ml and 500 ml) or of 1 or 6 bottles (1000ml)

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Sterofundin ISO Infusionslösung
Belgium	Sterofundin ISO oplossing voor infusie
Bulgaria	Sterofundin ISO
Cyprus	Sterofundin ISO
Czech Republic	Ringerfundin B.Braun
Denmark	Ringerfundin
Estonia	Sterofundin ISO
Finland	Ringerfundin infuusioneste, liuos
France	Isofundine, solution pour perfusion
Germany	Sterofundin ISO Infusionslösung
Greece	Sterofundin ISO
Hungary	Ringerfundin B. Braun infúzio
Italy	Sterofundin
Latvia	Sterofundin ISO
Lithuania	Sterofundin ISO infuzinis tirpalas
Luxembourg	Sterofundin Iso solution pour perfusion
Malta	Sterofundin ISO
Netherlands	Sterofundin ISO
Norway	Ringerfundin infusionsvaeske
Poland	Sterofundin ISO
Portugal	Isofundin, solución para perfusión
Romania	Sterofundin ISO soluție perfuzabilă
Slovenia	Sterofundin ISO raztopina za infundiranje
Slovakia	Ringerfundin
Spain	Isofundin, solución para perfusión
Sweden	Ringerfundin infusionsvästka, lösning
United Kingdom	Sterofundin ISO solution for infusion

This leaflet was last revised in February 2018.

The following information is intended for healthcare professionals only:

Symptoms associated with excessive overdose of the individual components of the solution

- Symptoms of hyperkalaemia
paraesthesia in extremities, muscle weakness, paralysis, cardiac arrhythmia, asystole, mental confusion.
- Symptoms of hypermagnesaemia:
loss of tendon reflexes and dyspnoea, nausea, vomiting, flushing of the skin, thirst, drop of blood pressure, drowsiness, confusion, muscle weakness, bradycardia, coma, cardiac arrest.
- Symptoms of hyperchloraemia:
loss of bicarbonate, acidosis.

- Symptoms of hypercalcaemia:
anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, polydipsia, polyuria, nephrocalcinosis, and, in severe cases, cardiac arrhythmia and coma. Too rapid injection of calcium salts may lead to chalky taste and hot flushes.
- Symptoms of excessive overdose of acetate and malate:
Metabolic alkalosis, which may lead to mood changes, tiredness, dyspnoea, muscle weakness, and cardiac arrhythmia, in the presence of low calcium levels also twitching and cramps.

Handling

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.

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.