

Package leaflet: Information for the user

Magnesium Sulphate Labesfal 1000 mg/10 ml solution for injection
Magnesium Sulphate Labesfal 2000 mg/10 ml solution for injection
Magnesium Sulphate Labesfal 2000 mg/20 ml solution for injection
Magnesium Sulphate Labesfal 2500 mg/10 ml solution for injection
Magnesium Sulphate Labesfal 4000 mg/20 ml solution for injection
Magnesium Sulphate Labesfal 5000 mg/20 ml solution for injection
Magnesium Sulphate Labesfal 5000 mg/10 ml solution for injection
Magnesium Sulphate Labesfal 10000 mg/20 ml solution for injection

Magnesium sulphate heptahydrate

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Magnesium Sulphate Labesfal is and what it is used for.

This medicine belongs to a group of medicines called “Electrolyte deficiency correctives. Magnesium”

Magnesium Sulphate Labesfal is used for:

Treatment of hypomagnesaemia when the oral route is not appropriated due to absorption disorders. Chronic alcoholism, malnutrition, severe diarrhoea or in patients with total parenteral nutrition.

2. What do you need to know before you use Magnesium Sulphate Labesfal Solution for Injection.

Do not use Magnesium Sulphate Labesfal

- if you are allergic (hypersensitive) to magnesium sulphate.
- if you suffer of cardiac arrhythmias, myocardial infarction or severe renal failure (creatinine depuration lower than 30 ml/min/1.73m²)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Magnesium Sulphate Labesfal

Intravenous use in children must be performed preferably in hospital environment.

Magnesium serum concentration must be monitored during the magnesium sulphate administration period.

In adults, in order to avoid a potentially lethal hypermagnesaemia, it is advisable to not exceed 0.6 mmol/min (about 150 mg/min). A new injection should not be performed before checking magnesium levels.

In renal failure, posology should be reduced and the renal function and magnesium levels should be checked.

Do not administer simultaneously calcium and magnesium by parenteral route.

Intravenous injection should be performed with the patient lying down with the head slightly elevated, to allow a better tolerance of the warm sensation that can occur according to the injection speed.

In severe hypomagnesaemia, magnesium sulphate should be administered through an infusion pump; blood pressure, respiratory rate, urinary output and the overdose signs (tendon reflex loss, asthenia, nausea, heat sensation, flush, vertigo and diplopia), must be monitored.

Other medicines and Magnesium Sulphate Labesfal

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Parenteral administration of magnesium salts may potentiate neuromuscular blockers or central nervous system depressors effects.

The following incompatibilities have been described; polymixin B sulphate, streptomycin sulphate, tobramycin sulphate, lipid emulsions, calcium gluceptate, calcium gluconate, dobutamine hydrochloride, procaine hydrochloride, tetracycline, soluble phosphates and alkaline carbonates and bicarbonates. It has also been referred incompatibility with benzyl penicillin and nafcillin since the magnesium sulphate effect is pH dependent.

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.

The safety in human pregnancy and breast-feeding was not established, so, as with other medicines, it is not advisable to use magnesium sulphate during pregnancy or breast-feeding unless it is considered absolutely necessary and always performed under medical vigilance.

Driving and using machines

No described effects.

3. How to use Magnesium Sulphate Labesfal

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Posology:

Adults – 6 to 8 mmol/day (1500 to 2000 mg/day), to modify according to the patient particular needs.

For intravenous use, in adults, a concentration up to 20% should be used; the administration rate should not exceed 1.5 ml/minute of a 10% solution or equivalent.

Children – 0.3 to 0.4 mmol/Kg/day

Magnesium sulphate has anticonvulsive properties when administered parenterally and can be used in the heptahydrate form to prevent or control the effects associated with acute uremia and eclampsia. Can be given intramuscularly at doses up to 5 g; can also be used by intravenous infusion with glucose 5%. The daily dose should not exceed approximately 30 to 40 g in patients with a normal renal function. Adequate dosage reductions should be performed for patients with renal failure.

Administration method:

- Slow intravenous injection
- For venous infusion, dilute in a glucose or saline solution.

The treatment should be interrupted as soon as magnesium level is normalized.

Serum magnesium levels should be checked during the magnesium sulphate administration.

Instructions for use and handling

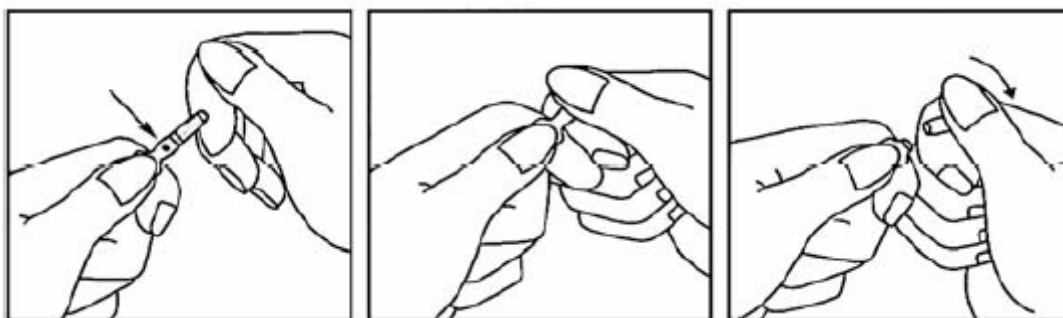
Medicinal products intended for parenteral administration should be visually inspected prior to use. It should only be administered if the solution is clear and without particles in suspension, and the container is intact.

This medicinal product is for single use only. Unused content should be disposed of immediately.

After opening the ampoule, the solution for injection should be used immediately.

Instructions to open the OPC ampoules (One-Point-Cut)

- Hold the ampoule body between your thumb and index finger, with the point facing upwards
- Put your other hand index finger supporting the upper part of the ampoule
- Put your thumb over the point, as shown in the figure below.
- With your index fingers close to each other, press the point area to open the ampoule.



If you use more Magnesium Sulphate Labesfal than you should

By intravenous route, mainly in the renal failure with anuria: hypermagnesaemia with cardiac rhythm disorders, respiratory depression, neuromuscular transmission disorders.

Treatment: rehydration, forced diuresis; in renal failures situations, haemodialysis or peritoneal dialysis.

Neuromuscular blocking associated with hypermagnesaemia can be reverted with the administration of calcium salts as calcium gluconate which can be administered by intravenous route in a dose equivalent to 2.5 to 5 mmol of calcium.

If you forget to use Magnesium Sulphate Labesfal

Do not use a double dose to make up for a forgotten dose.

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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

- Hypersensitivity reactions
- Hypocalcemia
- Pain in the injection site, vasodilatation with a warmth sensation.
- Hypermagnesemia potentially lethal in case of severe renal failure (see section 2." Do not use Magnesium Sulphate Labesfal") or very rapid injection (see section 2 "Warnings and precautions").

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to INFARMED, I.P. through the contacts below. When communicating side effects, you will be helping to improve safety information about this medicine.

INFARMED, I.P.

Direção de Gestão do Risco de Medicamentos

Parque da Saúde de Lisboa, Av. Brasil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Drug line: 800222444 (free call)

Fax: +351 21 798 73 97

Website:

<http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage>

Email: farmacovigilancia@infarmed.pt

5. How to store Magnesium Sulphate Labesfal

Store below 25°C.

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

Do not use this medicine after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Magnesium Sulphate Labesfal contains

- The active substance is magnesium sulphate heptahydrate.
- The other excipient is water for injections.

Magnesium Sulphate Labesfal 1000 mg/10 ml

Each ml of solution for injection contains 100 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 2000 mg/10 ml

Each ml of solution for injection contains 200 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 2000 mg/20 ml

Each ml of solution for injection contains 100 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 2500 mg/10 ml

Each ml of solution for injection contains 250 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 4000 mg/20 ml

Each ml of solution for injection contains 200 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 5000 mg/20 ml

Each ml of solution for injection contains 250 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 5000 mg/10 ml

Each ml of solution for injection contains 500 mg of magnesium sulphate heptahydrate.

Magnesium Sulphate Labesfal 10000 mg/20 ml

Each ml of solution for injection contains 500 mg of magnesium sulphate heptahydrate.

What Magnesium Sulphate Labesfal looks like and contents of the pack

Magnesium sulfate heptahydrate
500 mg/mL Solution for Injection (10ml)
(Labesfal, Lab. Almiro S.A.Portugal)
RH072

WHOPAR part 3
Suppliers submission of the
SRA approved text

November 2018

Magnesium Sulphate 1000 mg/10 ml
Packs of 6, 12, 50 and 100 type I glass, colourless, 10 ml solution for injection ampoules.

Magnesium Sulphate 2000 mg/10 ml
Packs of 6, 12, 50 and 100 type I glass, colourless, 10 ml solution for injection ampoules.

Magnesium Sulphate 2000 mg/20 ml
Packs of 6, 12, 50 and 100 type I glass, colourless, 20 ml solution for injection ampoules.

Magnesium Sulphate 2500 mg/10 ml
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Magnesium Sulphate 4000 mg/20 ml
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Magnesium Sulphate 5000 mg/10 ml
Packs of 6, 12, 50 and 100 type I glass, colourless, 10 ml solution for injection ampoules.

Magnesium Sulphate 10000 mg/20 ml
Packs of 6, 12, 50 and 100 type I glass, colourless, 20 ml solution for injection ampoules.

Marketing Authorisation Holder and Manufacturer

Labesfal - Laboratórios Almiro, S.A.
Zona Industrial do Lagedo
3465-157 Santiago de Besteiros
Portugal

This leaflet was last revised in
March 2018