

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Magnesium sulfate-Kalceks 500 mg/ml solution for injection, BP¹

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 healthcare provider.
- 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 healthcare provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Magnesium sulfate-Kalceks is and what it is used for

Magnesium sulfate-Kalceks solution for injection, BP contains the active substance magnesium sulfate heptahydrate (hereafter – magnesium sulfate).

Magnesium sulfate-Kalceks solution for injection, BP is used for:

- treatment of women with eclampsia
- prevention of eclampsia in women with severe pre-eclampsia
- prevention of cerebral palsy in the infant in women at risk of imminent preterm birth before 32 weeks of gestation

2. What you need to know before you receive Magnesium sulfate-Kalceks

Do not use Magnesium sulfate-Kalceks:

- if you are allergic to magnesium sulfate heptahydrate, its salts or any of the ingredients of this medicine (listed in section 6);
- if you suffer from heart block;
- if you suffer from a severe kidney disorder.

Warnings and precautions

Talk to your healthcare provider before using Magnesium sulfate-Kalceks:

- if you have muscular weakness called *myasthenia gravis*;

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory agency's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- if you use certain heart medicines or nervous system medicines. Be sure to tell your healthcare provider about these.
- if you have kidney disorders;

A safe regimen should include following conditions: presence of the deep tendon reflexes, good breathing at least 16 breaths per minute, sufficient amount of urine since the last dose. A calcium antidote should be ready if necessary.

When magnesium sulfate used in pregnant women, the fetal heart rate should be monitored.

Other medicines and Magnesium sulfate-Kalceks

Tell your healthcare provider if you are using, have recently used or might use any other medicines. Especially:

- heart medicines called beta-blockers;
- medicines called calcium-channel blockers, such as nifedipine;
- medicines to slow brain activity, such as barbiturates, opiates, general anaesthetics;
- medicines for treating heart failure and irregular heart beat called cardiac glycosides, such as digoxin.

There are several other medicines, including some antibiotics and aspirin, which should not be used with magnesium sulfate. Your healthcare provider will discuss these with you.

Magnesium sulfate-Kalceks with alcohol

Do not drink alcohol when receiving this product.

Pregnancy and breast-feeding

The baby's heart rate should be monitored. Continuous use of magnesium sulfate injection (beyond 5-7 days) during pregnancy may harm your baby.

Only a small amount of magnesium sulfate passes into breast milk. Therefore magnesium sulfate is compatible with breast-feeding.

Driving and using machines

No information is available on this.

Magnesium sulfate-Kalceks contains sodium hydroxide

This medicine is essentially "sodium-free."

3. How to use Magnesium sulfate-Kalceks

Your healthcare provider will decide how much magnesium sulfate you need and for how long. The dose of medicine should be individualised, and administration will be discontinued as soon as the optimal effect is achieved.

Magnesium sulfate can be administered by infusion into a vein, or injection into a muscle.

Your healthcare provider will prepare a diluted solution to a concentration of 20 % or less prior to administration by infusion into your vein. The diluents commonly used are 5 % glucose solution and 0.9 % sodium chloride solution.

Deep injection into muscle of the undiluted (50 %) solution is appropriate for adults.

If you get more Magnesium sulfate-Kalceks than you should

As this medicine is given to you by a healthcare provider, it is unlikely that you will be given more magnesium sulfate than you should.

Overdose of magnesium sulfate can cause breathing depression and loss of reflexes, as well as nausea, vomiting, flushing, thirst, low blood pressure, drowsiness, confusion, slurred speech,

double vision, muscle weakness, low heartbeat rate, irregular heartbeat, electrolyte/fluid abnormalities. In severe cases coma and cardiac arrest may occur.

Treatment

Assisted ventilation and injection of a calcium antidote may be given if this happens. Dialysis may be necessary in patients with kidney disorders or severely high magnesium.

4. Possible side effects

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

You may feel a flushing sensation when the medicine is given in a vein.
The medicine is painful when given in a muscle.

If your magnesium level is too high, you may have breathing depression, weakness, palpitations, altered consciousness or kidney effects. Your healthcare provider will monitor closely so that these are unlikely to occur.

5. How to store Magnesium sulfate-Kalceks

Do not store above 30 °C. Do not freeze.
Single use ampoules. Discard unused portion.

Keep out of the sight and reach of children.

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

The product should be used immediately.

Do not use this medicine if you notice haziness, discoloration, precipitation or visible particulate matter.

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

6. Contents of the pack and other information

What Magnesium sulfate-Kalceks contains

- The active substance is magnesium sulfate heptahydrate
1 ml of solution contains 500 mg of magnesium sulfate heptahydrate.
1 ampoule (10 ml) contains 5000 mg of magnesium sulfate heptahydrate.
- The other ingredients are 0.1 M solution of sulfuric acid/0.1 M solution of sodium hydroxide (till pH 5.5-7.0), water for injections.

What Magnesium sulfate-Kalceks looks like and contents of the pack

A clear colourless liquid.

10 ml of solution is filled in type I hydrolytic class colourless borosilicate glass ampoules with break line or open point cut. Ampoules could be marked with coloured rings.
5 ampoules are packed in a polyvinylchloride film liner and then one, two or twenty liners together with leaflet are placed in a cardboard box.

Not all pack sizes may be marketed.

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For any information about this medicinal product, please consult the MAH (see above).

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Section 6 updated in October 2019.

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Detailed information on this medicine is available on the World Health Organization (WHO) web site: <https://extranet.who.int/prequal/>