

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities (term to be revised).
The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

Information for the patient

[RH086 trade name]¹

Magnesium Sulfate Heptahydrate 500 mg/mL Solution for Injection

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

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care 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 seem to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [RH086 trade name] is and what it is used for
2. What you need to know before you are given [RH086 trade name]
3. How [RH086 trade name] is given
4. Possible side effects
5. How to store [RH086 trade name]
6. Contents of the pack and other information

1. What [RH086 trade name] is and what it is used for

[RH086 trade name] contains the active substance magnesium sulfate.

[RH086 trade name] is used for:

- preventing seizures in women with severe pre-eclampsia (high blood pressure associated with pregnancy);
- treatment of women with eclampsia (seizures as a result of pre-eclampsia);
- preventing cerebral palsy (a group of disorders that affect muscle movement and coordination) in the children of women at risk of imminent preterm birth before 32 weeks of gestation.

2. What you need to know before you are given [RH086 trade name]

Do not use [RH086 trade name]:

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

Warnings and precautions

Talk to your healthcare provider before using [RH086 trade name]:

- if you have muscle weakness caused by *myasthenia gravis*;
- if you take certain heart medicines or nervous system medicines. Be sure to tell your healthcare provider about the medicines you take;
- if you have kidney problems.

¹Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Before giving you a dose of this medicine, your doctor will ensure that you are safe to receive it by checking: the presence of the knee-jerk reflex (also called patellar reflex), that you are breathing well with at least 16 breaths per minute, that you have produced a sufficient amount of urine since the last dose.

If the medicine causes serious side effects, an antidote (a calcium solution) should be kept ready to treat you.

When magnesium sulfate is used in pregnant women, the baby’s heart rate should be monitored.

Other medicines and [RH086 trade name]

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, usually to treat high blood pressure, such as nifedipine or nimodipine;
- 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.

[RH086 trade name] with alcohol

Do not drink alcohol when receiving this product.

Pregnancy and breast-feeding

Pregnancy

The baby’s heart rate should be monitored.

Continuous use of magnesium sulfate injection (beyond 5-7 days) during pregnancy may harm your baby.

Breastfeeding

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.

Excipients

This medicine contains less than 1 mmol sodium (23 mg) per ampoule, i.e. essentially 'sodium-free'

3. How [RH086 trade name] is given

Your health care provider will decide how much [RH086 trade name] you need and for how long.

[RH086 trade name] can be given by infusion into a vein, or injection into a muscle; your health care provider will also decide on the best way to give it to you.

If it needs to be given into a vein, your health care provider will prepare a diluted solution (concentration of 20% or less) before giving you this medicine. The diluents commonly used are 5% glucose solution and 0.9% sodium chloride solution.

For deep injection into a muscle, the undiluted (50%) solution is appropriate. Because the medicine may be painful when injected into a muscle, your health care provider will mix it with a medicine to numb the pain.

If you get more [RH086 trade name] than you should

As this medicine is given to you by a health care 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 of overdose

Assisted ventilation and injection of an antidote (a calcium solution) 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 to you into a vein and you will have a feeling of warmth when the medicine is given into a muscle.

The medicine may be painful when injected into a muscle.

If your magnesium levels are too high, you may have breathing depression, loss of reflexes, weakness, low heartbeat rate, irregular heartbeat, drowsiness, confusion, slurred speech, double vision, nausea and vomiting, thirst and kidney effects. Your healthcare provider will monitor you closely for these effects.

Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [RH086 trade name]

Keep this medicine out of the sight and reach of children.
Do not store above 30 °C. Do not freeze.

This medicine must not be used after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [RH086 trade name] contains

- The active substance is magnesium sulfate heptahydrate
- The other ingredients of [RH086 trade name] are:
0.5M solution of sulfuric acid and/or 0.1M solution of sodium hydroxide (for adjustment of pH)
Water for injections

What [RH086 trade name] looks like and contents of the pack

10 ml of solution is filled in type I hydrolytic, colourless borosilicate glass ampoules with an open point cut or colour breaking circle.

5 ampoules are packed in a polyvinylchloride film or polyethylene terephthalate film liner. Such 2 liners together with a leaflet are then placed in a cardboard box.

Supplier and Manufacturer

Joint Stock Company “Halychpharm”
6/8, Opryshkivska Str., Lviv, 79024, Ukraine
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Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal/>.