

Package leaflet: Information for the user
Magmedi 97 mg tablets
magnesium

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 any further questions, ask your doctor or pharmacist.
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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Magmedi is and what it is used for

Magmedi contains the active ingredient magnesium citrate nonahydrate equivalent to 97.2 mg (4 mmol) of magnesium.

Magmedi is intended for the treatment and prevention of magnesium deficiency in adults, adolescents and children aged from 12 years.

Magnesium is an essential mineral which is particularly important in nerve and muscle function in addition to other activities within the body.

You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

Magmedi is not intended for the treatment of either severe magnesium loss (blood magnesium level is less than 0.4mmol/L) or severe symptoms. Treatment with oral magnesium can begin when blood magnesium levels rise above 0.4mmol/L or when the severe symptoms are no longer present.

2. What you need to know before you take Magmedi

Do not take Magmedi

- if you are allergic to magnesium citrate nonahydrate or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems

Warnings and precautions

Talk to your doctor or pharmacist before taking Magmedi:

- if you suffer from kidney problems.
- if you suffer from heart problems.
- If you have confirmed magnesium deficiency as you may also have low calcium and low potassium levels.
- If you suffer any side effects such as diarrhoea, treatment should be temporarily interrupted and can be restarted after improvement and /or elimination of the symptoms with a reduced dosage.

- If you have switched from another magnesium medicine to ensure that treatment with Magmedi does not make you feel unwell and that you can continue to receive the correct dose of magnesium.

Other medicines and Magmedi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Magmedi can affect the way some other medicines work. Also, some other medicines can affect the way Magmedi works.

In particular, you must allow a time interval of **2-3 hours** between taking Magmedi and the following medicines.

- **Cellulose sodium phosphate**, used to prevent kidney stones
- **EDTA**, used in hospital for high calcium levels
- **Fluorides**, used for preventing tooth decay
- **Tetracycline**, an antibiotic to treat infections

In order to avoid reduced absorption, magnesium preparations should be taken 3 to 4 hours before or after taking the following medicines.

- **Nitrofurantoin, Nitroxoline**, antibiotics to treat infections
- **Aminoquinolines**, medicines to treat malaria
- **Quinidine and quinidine derivatives**, medicines to treat heart rhythm disorders
- **Penicillamine**, medicine used to treat severe rheumatoid arthritis and used in Wilson's disease
- **Iron**, to treat anemia
- **Bisphosphonates**, to treat osteoporosis
- **Eltrombopag**, to correct bleeding deficiency

The following medicines may cause **magnesium deficiency**. Your doctor may decide to adjust your daily dose of magnesium.

- **Aminoglycosides**, antibiotics used to treat infections e.g. gentamicin, tobramycin and amikacin
- **Certain medicines used to treat cancer** such as cisplatin, carboplatin and EGF-receptor antagonists such as cetuximab, erlotinib and panitumumab.
- **Ciclosporins and Tacrolimus**, medicines used to suppress the body's immune system e.g. following an organ transplant
- **Water tablets (Diuretics)**, medicines used to treat blood pressure or heart failure e.g. thiazide, furosemide
- **Proton Pump Inhibitors**, medicines used to treat high acid in the stomach or oesophagus. e.g. omeprazole, esomeprazole, lansoprazole, pantoprazole
- **VEGF-blockers** such as bevacizumab
- **PD-1 inhibitors** such as Nivolumab
- **Amphotericin B**, antibiotic that fights fungal infections in the body
- **Rapamycin**, medicine used to suppress the body's immune system e.g. following an organ transplant
- **Pentamidine**, medicine to treat infections such as pneumonia
- **Foscarnet**, an antiviral medication

Disorders that may influence the level of magnesium in the body include:

- diabetes
- over-active thyroid
- too much aldosterone produced by the adrenal glands

Pregnancy, breast-feeding and fertility

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.

Magmedi can be used during pregnancy and during breast-feeding without concerns. Based on long-term experience, no effects of magnesium on male and female fertility are anticipated.

Driving and using machines

Magmedi has no or negligible influence on the ability to drive and use machines.

3. How to take Magmedi

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

The recommended dose is

Adults (over 18 years) 1-2 tablets 3 times daily (equal to 291.6 – 583.2 mg magnesium).

Use in children and adolescents

Children and Adolescents (12 to 18 years) 1 tablet 3 times daily (equal to 291.6 mg magnesium)
Magmedi tablets are not recommended for children less than 12 years. Other form(s) of this medicine may be more suitable for children under 12 years; ask your doctor or pharmacist.

As older patients may have reduced kidney function, dose adjustment may be necessary depending on their kidney function as detailed in section Renal patients below.

Renal patients:

Do not take Magmedi if you have severe renal failure.

No change to the recommended dose is required if you have mild to moderate renal failure.

The blood magnesium levels of children and adolescents (12 to 18 years) and renal patients need to be monitored at regular intervals.

The duration of magnesium supplementation will depend upon the clinical needs of each patient.

Directions for use:

Tablets for oral use.

The tablet may be broken in half using the score line. The score line is only there to help you break the tablet if you have difficulty swallowing it whole, not to divide into equal parts.

If you take more Magmedi than you should

No side effects are expected in cases where the kidneys are fully functioning. Any excessive amount of magnesium will be excreted through your kidneys.

If you have taken more of this medicine than directed, or if a person with severe kidney problems, or if a child accidentally has taken this medicine, please contact your doctor or local hospital

casualty department for judgement of the risk and advice. Symptoms may include: light-headedness/dizziness, nausea, vomiting, drowsiness, shortness of breath and cardiac arrest.

If you forget to take Magmedi

Do not take 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.

Common (may affect up to 1 to 10 people): Soft stools or diarrhoea following high doses.

Very rare (may affect up to 1 in 10,000 people): Fatigue if Magmedi is used long-term.

If you get any side effects such as diarrhoea, you should discuss this with your doctor or a pharmacist. Your doctor may temporarily interrupt your treatment with Magmedi. After the symptoms improve your doctor may recommend that you restart treatment, with a reduced dosage.

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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Magmedi

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. 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 Magmedi contains

- The active substance is magnesium. Each tablet contains magnesium citrate nonahydrate equivalent to 97.2 mg (4 mmol) magnesium.
- The other ingredients are mannitol (E421), copovidone, microcrystalline cellulose (E460(i)), magnesium stearate (E572).

What Magmedi looks like and contents of the pack

White, oblong tablet, marked with “Mg” and “97” on either side of a score line on one side.

Dimensions: 18 mm x 8.7 mm. Magmedi is available in packs of 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Kora Corporation Ltd t/a Kora Healthcare

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Dublin 2,
D02 H364,
Ireland

Manufacturer

Lusomedicamenta Sociedade Tecnica Farmaceutica, S.A.
Estrada Consiglieri Pedroso, 69 - B, Queluz de Baixo, Barcarena,
2730-055, Portugal

This medicinal product is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Ireland, Belgium, Netherlands	Magmedi 97 mg tablets
United Kingdom (Northern Ireland)	Magnesium Kora Healthcare 4 mmol (97 mg) tablets

This leaflet was last revised in March 2022