

PATIENT INFORMATION LEAFLET

MAGNEZINC 30 mg/300 mg Film Coated Tablet For oral use.

- **Active substance(s):** Each film tablet contains 82.6 mg zinc sulfate monohydrate equivalent to 30 mg zinc and 520.4 mg magnesium oxide equivalent to 300 mg magnesium.
- **Excipient(s):**
Tablet: Lactose monohydrate (derived from cow's milk), corn starch, croscarmellose sodium, polyethylene glycol, povidone K30.
Coating material: Hypromellose, titanium dioxide (E171), polyethylene glycol, lacquer carmoisine (E122).

Read this PATIENT INFORMATION 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

1. What **MAGNEZINC** is and what it is used for?
2. What you need to know before you take **MAGNEZINC**?
3. How to take **MAGNEZINC**?
4. Possible side effects
5. How to store **MAGNEZINC**?

1. What MAGNEZINC is and what it is used for?

- **MAGNEZINC** is an oral tablet containing zinc sulfate monohydrate and magnesium oxide.
- Each film tablet contains 82.6 mg zinc sulfate monohydrate equivalent to 30 mg zinc and 520.4 mg magnesium oxide equivalent to 300 mg magnesium.
- Each box contains 4 blisters containing a total of 40 tablets. It is used to eliminate or prevent zinc and magnesium deficiency, to treat excessive copper accumulation in the body (Wilson) and/or zinc absorption disorder (acrodermatitis enteropathica).

2. What you need to know before you take MAGNEZINC?

Do not use MAGNEZINC in the following conditions

If;

- You have severe kidney insufficiency
- You are allergic (hypersensitivity) to any of the other ingredients of **MAGNEZINC**.

Warnings and precautions

If;

- you have been told by your doctor that you have kidney failure
- you are pregnant or you are breastfeeding
- you have been told by your doctor that you have an intolerance to some sugars

It is not appropriate to use zinc in adult diarrhoea of unknown cause.

Products containing 30 mg zinc are not suitable for the treatment of diarrhoea in children due to the high amount of zinc given at one time.

If these warnings apply to you, even if at any time in the past, please consult your doctor.

MAGNEZINC with food and drink

Whole-grain, fiber-based foods and dairy products should not be used with MAGNEZINC since they reduce the absorption of MAGNEZINC.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

MAGNEZINC can be used as a zinc and magnesium supplement with a doctor's recommendation during pregnancy.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

MAGNEZINC can be used under doctor supervision during breastfeeding.

Driving and using machines

There is no effect on ability to drive and use machine.

Important information about some of the excipients of MAGNEZINC

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MAGNEZINC since it contains lactose.

It may cause allergic reactions due to the content of lacquer carmoisine (E122).

Other medicines and MAGNEZINC

Co-intake of tetracyclines, quinolones, and penicillamines with zinc and magnesium salts may result in the reduction of the effect of MAGNEZINC; therefore these substances should be taken 2 hours before or after MAGNEZINC.

High doses of iron preparations should not be used together with MAGNEZINC as these prevent the absorption of MAGNEZINC.

Contraceptive medicines can reduce blood zinc levels.

It should not be used at the same time as the following medicines because it contains magnesium:

Diuretics (diuretics), aminoglycosides (gentamicin, tobramycin, amphotericin B) which are a kind of antibiotics, immunosuppressants that suppress the immune system (cyclosporine A), and

cytostatics (cisplatin) used in cancer treatment should not be used because they cause increased magnesium loss in the kidney.

Since it increases magnesium absorption, non-steroidal anti-inflammatory drug (NSAID) indomethacin, which is used in the treatment of rheumatic diseases, should not be taken.

When the drugs containing levothyroxine which is used in the treatment of thyroid diseases, are taken with MAGNEZINC, the two drugs should be taken at least 2 hours apart as the absorption of MAGNEZINC is impaired.

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to take MAGNEZINC?

- **Instructions for use and dosage/frequency of administration:**

MAGNEZINC should be taken once a day for adults.

If you have Wilson's disease, use up to 5 tablets per day (150 mg/day, in 3 divided doses) and if you have Acrodermatitis Enteropathica, use 2-5 tablets per day (50-150 mg/day).

Unless recommended otherwise by your doctor, use at the indicated doses.

- **Route of administration and method:**

MAGNEZINC is for oral use.

- **Different age groups:**

Use in children:

The safety and efficacy of MAGNEZINC has not been studied in children.

Use in elderly:

The safety and efficacy of MAGNEZINC has not been studied in elderly.

- **Special cases of uses:**

Kidney failure

The efficacy and safety of zinc in patients with renal failure have not been studied.

MAGNEZINC should not be used in the case of moderate kidney failure or the dose should be reduced; because the risk of toxic effect increases.

Liver failure

The efficacy and safety of zinc in patients with hepatic failure have not been studied.

MAGNEZINC should not be used in the case of coma in the liver if there is a risk of kidney failure.

If you have impression that the effect of MAGNEZINC is very strong or weak, tell a doctor or pharmacist.

If you take more MAGNEZINC than you should:

If you take more MAGNEZINC than you should, tell your doctor or pharmacist.

If you take more MAGNEZINC than you should; nausea, vomiting, abdominal pain and diarrhea can be seen. Drowsiness, discoloration or gray-blue discoloration of the skin (cyanosis) and even shock may develop.

If you forget to take MAGNEZINC:

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

If you stop taking MAGNEZINC:

When the treatment with MAGNEZINC is stopped, no adverse effects are expected.

4. Possible side effects

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

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking MAGNEZINC and immediately inform your doctor or go to the nearest emergency department:

- Swelling in hands, feet, wrists, face and lips, especially when the mouth or throat swells to making it difficult to swallow or breathe

These are all very serious side effects.

If you have any of them, this means you have serious allergy to MAGNEZINC. You may need emergency medical care or hospitalization.

These very serious side effects occur very rarely.

If you notice any of the following immediately inform your doctor or go to the nearest emergency department.

- Low blood pressure (hypotension)
- Heart rhythm disorder (arrhythmia)
- Electrocardiographic changes (in the electrical activity of the heart) in potassium deficiency

These are all serious side effects. They may require emergency medical treatment.

These serious side effects occur very rarely.

If you experience any one of the followings tell your doctor:

Common

- Vomiting
- Darkness in stool color

Rare

- Gastrointestinal irritation
- Nausea
- Diarrhea

- Constipation
- Bloating (epigastric fullness) in the stomach

Very rare

- Dyspepsia
- Heartburn

These are mild effects of MAGNEZINC.

These side effects disappear when the dose is reduced or treatment is discontinued.

Reporting of side effects

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 via clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. How to store MAGNEZINC?

Keep in the original package and out of the reach and sight of children.

Store in room temperature below 25°C.

Use in accordance with expiry date.

Do not use MAGNEZINC after the expiry date which is stated on the package.

Do not use MAGNEZINC if you notice any damage to the product and/or package.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

Berko İlaç ve Kimya San. A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul

0 216 456 65 70 (Pbx)

0 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya San. A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul

0 216 592 33 00 (Pbx)

0 216 592 00 62 (Fax)

This patient information leaflet was approved on 28/01/2022.