

PATIENT INFORMATION LEAFLET

MAGOSIT 365 mg tablets

For oral use.

- **Active substance:** Each tablet contains 605.33 mg magnesium oxide equivalent to 365 mg magnesium ion.
- **Excipients:** Poloxamer P188, lactose monohydrate (obtained from cow milk), polyethylene glycol 8000, low substituted hydroxypropyl cellulose, copovidone and magnesium stearate

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.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher or lower** doses other than what is recommended to you.*

What is in this leaflet:

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

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

MAGOSIT contains magnesium oxide as active substance.

Magnesium belongs to the medicine group of mineral supporting products.

Almost white, gray stained, round tablets are presented in transparent PVC/PE/PVDC -Aluminum foil blisters. Each cardboard box contains 30 tablets. MAGOSIT is indicated in the treatment of,

- Ameliorating the symptoms occurred in deficiency of magnesium
- Heart and vascular system: Heartbeat acceleration, heartbeat irregularities, heart attack, angina pectoris (breast pain occurring from constriction/blockage of the veins feeding heart), mild severe hypertension
- Nerve and muscles: Sudden and excess spasm in muscle (tetani), spasm formation in muscle, stomach-intestine cramps, increased stimulability of muscle and nerves, calf cramps, cases with cramps and stress in new-born or small children

- Gynecological diseases, related to birth and baby: Preterm spasms, cervical failure, early membrane rupture, spasm in pregnancy (eclampsia [disease with seizure attacks, increase of blood pressure, protein presentation in urine and water holding of the body]/pre-eclampsia [disease with increase of blood pressure in pregnancy, protein presentation in urine and water holding of the body]), tocolysis necessary to use betamimetic (stopping spasm of womb), menstrual period with pain
- Orthopedics: Calcification and ossifications
- Prevention of renal calculus formation: Prevention of renal calculus formation (prevention of repetition of calcium oxalate urolithiasis)
- Treatment of diabetic and migraine (a type of headache)

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

DO NOT take MAGOSIT

If;

- You have a hypersensitivity (allergic) to any of the ingredients of MAGOSIT
- You have severe renal failure or insufficiency

Take special care with MAGOSIT in the following conditions

If;

- You have severe renal failure, tell your doctor before using this medicine
- You use Digitalis group medicines used in heart failure
- You take Lithium treatment for change of emotion and control of depression state due to excitement disorder
- Your magnesium level is under 1.5 mEq/L
- It may cause diarrhea due to usage of the medicine in patients above middle age. Tell your doctor in case of diarrhea occurrence

Please consult your doctor, even if these statements were applicable to you at any time in the past.

MAGOSIT with food and drink

MAGOSIT should be taken with food. Usage in fasting condition may cause diarrhea.

Pregnancy

Consult your doctor or pharmacist for advice before using the medicine.

Do not use MAGOSIT during pregnancy without consulting your doctor.

If you notice that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist for advice before using the medicine.

Do not use MAGOSIT during breast-feeding without consulting your doctor.

Driving and using machines

MAGOSIT does not affect your ability to drive or operate machines.

Important information about on some of the ingredients of MAGOSIT

Due to MAGOSIT contains lactose monohydrate, if you have been previously told by your doctor that you have an intolerance to some sugars in MAGOSIT, consult your doctor before taking MAGOSIT.

Using with other medicines

Other drugs may affect the treatment with MAGOSIT. Before taking magnesium oxide, talk to your doctor if you are taking;

- Muscle relaxant drugs (non-depolarize neuromuscular blockers)
- Some antibiotic (amino quinolones, nitrofurantoin, penicillamine, tetracyclines, fluoroquinolones)
- Digoxin (heart failure treatment)
- Lithium (change of emotion and control of depression state)
- Sodium polystyrene sulfonate (provides elimination of potassium)
- Cellulose sodium phosphate (used to prevent kidney stones)
- Other medicines containing magnesium (including magnesium enemas)
- Barbiturate (drugs used for the treatment of sleeplessness), opioids (substances acting as morphine), hypnotics (somnific drugs)
- Nifedipine (drugs used in hypertension or heart problems)
- The absorption of levothyroxine containing drugs which are used in the treatment of thyroid diseases, is impaired when used concomitantly with MAGOSIT, therefore at least 4 hours interval is required between the use of these two drugs.

Please tell your doctor or pharmacist if you are currently taking or have recently taken any other medicines, with or without a prescription.

3. How to take MAGOSIT?

- **Instructions for appropriate method and dose/frequency of administration:**

If the doctor recommend as otherwise;

Daily dose is 1-2 tablet for adults and adolescents (12-17 aged).

Recommended daily dose during pregnancy and breast-feeding period is 1-2 tablet.

- **Route and method of administration:**

MAGOSIT is only for oral administration.

- **Different age groups:**

- **Use in children:**

Recommended daily dose for children older than 12 age is 1-2 tablet.

- **Usage in elderly:**

There is no data about usage in older population.

- **Special populations:**

Kidney failure:

Do not take MAGOSIT in the patient with severe kidney failure.

Liver failure:

There is no data about usage in the patients with liver failure.

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

If you take more MAGOSIT than you should

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

If you forget to take MAGOSIT

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

Possible effects when MAGOSIT treatment is stopped

Do not stop MAGOSIT without consulting your doctor.

4. Possible side effects

Like all medicines, side effects can be seen in people who are sensitive to substances in the content of MAGOSIT.

Side effects were listed as shown in the following categories:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

If any of the following takes place, stop taking MAGOSIT and immediately contact your physician or apply to the emergency department of the nearest hospital:

- Severe allergic reaction (ex. Mouth and throat swelling, itching, eruption, rash)
- Slow and superficial breathing (respiratory depression)
- Loss of consciousness (coma)

These are all very serious side effects.

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

These very severe side effects have been seen quite rarely.

If you experience any of the following side effects, immediately contact your physician or apply to the emergency department of the nearest hospital:

- Low blood pressure
- Changes in electrical efficacy of heart (ECG),
- Depression

These are all severe side effects. Emergency medical intervention may be necessary. Severe side effects have been seen quite rare.

Tell your doctor if you notice any of the following:

Common

- Nausea
- Vomiting
- Wooziness

Very Common

- Diarrhea

Unknown

- Cramp
- Feeling of tiredness
- Weakness

These are mild side effects of MAGOSIT.

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

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

5. How to store MAGOSIT?

Store MAGOSIT in the package and keep out of the reach and sight of children.

Store below 25°C at room temperature and in a dry place.

Use in accordance with the expiry date.

Do not use MAGOSIT after the expiry date which is stated on the blister or package.

Marketing authorization holder:

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This patient information leaflet was last approved on 04/05/2021.