



PACKAGE LEAFLET: INFORMATION FOR THE USER

MAGNESIE CALCINEE 400 mg Powder for Suspension

Taken by mouth.

Active substance: Each dose contains 400 mg magnesium hydroxide.

Excipients: MAGNESIE CALCINEE does not contain any excipients.

Read all of this PACKAGE 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. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you.*

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1. WHAT MAGNESIE CALCINEE IS AND WHAT IT IS USED FOR

MAGNESIE CALCINEE is in the form of white, odorless, tasteless, fine-structured, fluid powder and is used after diluting.

MAGNESIE CALCINEE contains magnesium which is a type of mineral, and is used in the following situations:

- Flatulence (gas in stomach and intestines)
- Heartburn
- Dyspepsia (indigestion)
- Constipation treatment due to its mild laxative (softening) effect

2. BEFORE YOU TAKE MAGNESIE CALCINEE

DO NOT take MAGNESIE CALCINEE if you have:

- Hypersensitivity to magnesium hydroxide,
- Symptoms of severe stomach pain, nausea, vomiting, appendicitis, diarrhea, or rectal bleeding of unknown cause,
- Severe kidney failure.

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

Taking MAGNESIE CALCINEE with food and drink:

No food or drink restriction is required during the use of MAGNESIE CALCINEE, unless advised otherwise by the doctor.



Pregnancy

Consult your doctor or pharmacist before taking this medicine.

It should not be used in the first 3 months of pregnancy. However it can be used in the last 6 months of pregnancy provided if long-term exposure to high doses is avoided. Magnesium supplementation during pregnancy has a significant effect on the diseases which may occur in baby and mother before or after birth, and magnesium supplementation reduces pregnancy-related leg cramps.

If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Driving and using machines

There is no reason to suspect a condition that would affect the ability to drive or use machines.

Important information regarding some of the ingredients of MAGNESIE CALCINEE

There are no ingredients which require special warnings or precautions.

Taking other medicines

No other drugs should be taken by mouth within 2-3 hours after taking "MAGNESIE CALCINEE", since magnesium salts will affect the treatment by reducing the absorption of some other drugs taken at the same time. These drugs are;

- ACE inhibitors used to treat hypertension (high blood pressure): captopril, enalapril and fosinopril,
- Some antibacterials (drugs used to treat bacterial diseases) and antifungals (drugs used to treat fungal diseases): azithromycin, cefaclor, cefpodoxime, isoniazid, itraconazole, nitrofurantoin, rifampicin, tetracycline, ketoconazole and quinolone antibacterials group,
- Antivirals (drugs used to treat viral diseases): atazanavir, fosamprenavir, tipranavir,
- Antihistamines used to treat allergies (fexofenadine),
- Drugs used to treat osteoporosis (bone loss): bisphosphonates,
- Corticosteroids (drugs used to suppress the immune system for various reasons): deflazacort,
- Drugs used to treat various heart diseases: digoxin, dipyridamole,
- Drugs used for pain relief: diflunisal,
- Antiepileptics (drugs used to treat epilepsy): gabapentin, phenytoin,
- Drugs used to treat ulcers: lansoprazole,
- Drugs used to treat thyroid gland-related diseases: levothyroxine,
- Drugs used after organ transplants: mycophenolate,
- Iron preparations,
- Lipid-regulating drugs: rosuvastatin,
- Antipsychotics (drugs used to treat various psychiatric diseases): sulpiride, phenothiazines,
- Drugs used to treat malaria: chloroquine, hydrochloroquine, proguanil,
- Therapeutic agent-containing drugs such as penicillamine.

Concomitant use with sodium polystyrene sulfonate, which is used to treat high potassium levels in the blood, may cause metabolic alkalosis (a disease manifested by slow and shallow breathing, tetany, and muscle hypersensitivity). Concomitant use of nilotinib (a type of drug used in cancer treatment)

with antacids should be avoided.

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

3. HOW TO TAKE MAGNESIE CALCINEE

Instructions for proper use and dose/frequency of administration

1 dose contains 400 mg magnesium hydroxide.

Unless advised otherwise by the doctor:

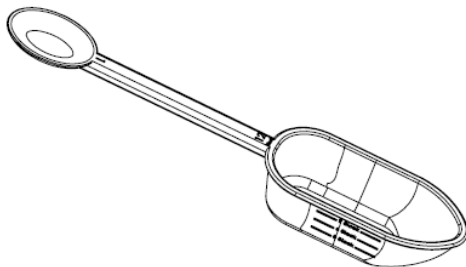
- In order to balance stomach acid (antacid) in adults and children over 12 years of age:
It is used 1 to 3 doses every 4 hours. It can only be taken up to 4 times a day.
- As a laxative for the treatment of constipation in adults and children over 12 years of age:
It is used 6 to 12 doses before going to bed.

Route and method of administration

The powder in the recommended dose is taken by mixing it in a glass of water.

Using the spoon:

As seen in the figure, the spoon in the box is used on both sides. The small side is for 1 dose. On the other side, there are measuring marks for 3, 6, 9 and 12 doses. The spoon should be used as described.



Different age groups

Use in children:

Not recommended for use in children under 12 years of age.

Use in the elderly:

It should be used with caution in elderly patients.

Special conditions

In patients with kidney failure:

It should not be used in severe kidney failure.

In patients with liver failure:

It should be used with caution in patients with liver dysfunction.



If you have the impression that the effect of MAGNESIE CALCINEE is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAGNESIE CALCINEE than you should

If you have used more MAGNESIE CALCINEE than you should, talk to a doctor or pharmacist or go to the hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people with hypersensitivity to the ingredients of MAGNESIE CALCINEE.

If any of the following occurs, stop using MAGNESIE CALCINEE and inform your doctor IMMEDIATELY or go to the emergency department of the nearest hospital:

- Swelling of the hands, wrists, feet, ankles, lips or face.
- Swelling of the mouth or throat that makes it difficult to swallow or breathe.

Side effects are classified in the following frequencies:

Very common	: affects at least 1 in 10 patients
Common	: affects 1 to 10 patients in 100
Uncommon	: affects 1 to 10 patients in 1000
Rare	: affects 1 to 10 patients in 10.000
Very rare	: affects less than 1 patient in 10,000
Unknown	: cannot be estimated from the available data.

Common: Diarrhea

Rare: Spasm-like stomach pain

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

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of ‘Side Effect Reporting for Medicines’ at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MAGNESIE CALCINEE

Keep MAGNESIE CALCINEE out of reach and sight of children and in its original pack.

Store at room temperature below 25°C.

Use this medicine in line with the expiry date.

Do not use MAGNESIE CALCINEE after the expiry date which is stated on the pack.

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.



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