

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed without a doctor's prescription

Maalox Plus Chewable Tablets

Active ingredients

Each tablet contains:

200 mg aluminium oxide hydrated

200 mg magnesium hydroxide

25 mg dimethicone

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Call your doctor if your symptoms of illness get worse or do not improve within two weeks.

1. What is this medicine intended for?

Maalox Plus Tablets are used as an antacid, antiflatulent, and to relieve the sensation of heartburn.

Therapeutic group:

Aluminium oxide and magnesium hydroxide: antacids.

Dimethicone (which converts into simethicone which is the active derivative): antiflatulent.

Maalox Plus Tablets work by reducing the amount of acid in your stomach. The antiflatulent agent in Maalox Plus Tablets helps to remove gas from your stomach.

2. Before using this medicine

Do not use this medicine if you:

- are allergic (sensitive) to aluminium oxide, magnesium hydroxide, simethicone, or any of the other ingredients in this medicine (see section 6). Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- are feeling very weak and have no energy
- have kidney problems/kidney failure

Do not take this medicine if any of the above conditions apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Special warnings about using this medicine

Talk to your doctor or pharmacist before starting treatment if you are on a low-phosphorous diet.

Children and adolescents

Maalox Plus Chewable Tablets are not intended for children.

Interactions with other medicines

If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Do not take Maalox Plus Tablets at the same time as other medicines. This is because some medicines may be affected by Maalox Plus Tablets or they may affect how well Maalox Plus Tablets will work.

Particularly tell your doctor or pharmacist if you are taking:

- heart medicines such as digoxin, quinidine, metoprolol, atenolol, and propranolol
- medicines for anaemia such as iron salts
- medicines used to treat stomach ulcers and acidity, such as ranitidine or cimetidine (H2 antagonists)
- medicines for malaria such as chloroquine, hydroxychloroquine
- medicines for some bone disorders, such as bisphosphonates
- medicines used to treat some allergic, inflammatory, or abnormal immune reactions, such as glucocorticoids
- medicines for kidney disorders, such as citrates
- medicines for tuberculosis, such as ethambutol, isoniazid
- medicines used to treat infections, such as fluoroquinolones, lincosamides, ketoconazole, cyclines including tetracyclines, cephalosporins (cefpodoxime and cefdinir), dolutegravir, elvitegravir, raltegravir potassium, rifampicin, antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, rilpivirine
- medicines used to treat mental illness (psychosis), such as phenothiazines, neuroleptics
- medicines used to treat increased amounts of potassium in the body, such as polystyrene sulfonate
- medicines for pain such as diflunisal, indomethacin
- medicines used in dental care, such as sodium fluoride
- medicines used to treat an underactive thyroid gland, such as levothyroxine
- medicines used to treat joint pain and abnormal chemical reactions in the body, such as penicillamine
- medicines used to reduce cholesterol such, as rosuvastatin
- medicines for cancer such as nilotinib, dasatinib monohydrate
- medicines used to treat blood disorders, such as eltrombopag olamine
- medicines for high blood pressure in the lungs (pulmonary hypertension), such as riociguat
- salicylates including aspirin
- vitamins

As a precaution, allow at least 2 hours (4 hours for the fluoroquinolones) between any medicine and the antacid.

Using this medicine and food

Take the tablet 20 minutes to one hour after meals and at bedtime.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if:

- you are pregnant, might become pregnant, or think you may be pregnant
- you are breast-feeding or plan to breast-feed.

Important information about some of this medicine's ingredients

Each tablet contains glucose (500.5 mg), sucrose (75 mg), and sorbitol (50 mg). Sorbitol is a source of fructose.

If your doctor has told you that you have an intolerance to or the inability to digest some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before using this medicine.

This medicine may be harmful to teeth.

Maalox Plus Tablets contain less than 1 mmol sodium (23 mg) per tablet, so are considered "sodium-free".

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

This medicine is taken by mouth. **Chew** the tablets **well** before swallowing.

The recommended dosage is usually:

Recommended dosage for adults and the elderly:

one or two tablets 4 times a day, 20 minutes to one hour after meals and at bedtime, or as directed by your doctor.

Do not exceed the recommended dose.

If the symptoms do not go away, talk to your doctor. Do not take this medicine for longer than two weeks unless directed by your doctor.

Maalox Plus Chewable Tablets are not intended for children.

If you have accidentally taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. If this happens you may get diarrhoea, stomach pain, bloating and cramping in the abdomen (stomach), vomiting, indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by an obstruction or blockage of the bowel.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Maalox Plus Tablets may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop taking this medicine and see a doctor or go to a hospital straight away if:

You have a red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing. This could be an allergic reaction. The frequency of this side effect is unknown.

Talk to your doctor or pharmacist if any of the following side effects get worse or last longer than a few days:

Uncommon side effects (affect up to 1 in 100 users):

- constipation
- diarrhoea

Very rare side effects (affect up to 1 in 10,000 users):

- Hypermagnesaemia (high level of magnesium in the blood), including observations after prolonged use in patients with impaired kidney function.

Side effects of unknown frequency (side effects whose frequency has not been established yet):

- hypophosphataemia – low level of phosphate in the blood. It may occur with high doses of the product or even at normal doses, especially in patients who are on low phosphorus diets
- hyperaluminemia – an electrolyte disturbance in which there is an abnormally elevated level of aluminium in the body
- abdominal pain.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C. Keep in the original package to protect from moisture.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

glucose anhydrous, maize starch, mannitol, sucrose, sorbitol liquid non-crystallizing, sorbitol, talc, magnesium stearate, pregelatinized starch (maize starch), lemon flavour, citric acid anhydrous, saccharin sodium, Swiss cream flavour, iron oxide yellow (E-172).

What the medicine looks like and contents of the pack:

White/yellowish tablets with 'Maalox' embossed on one side.

Quantity in pack: 40 or 50 tablets. Not all pack sizes may be marketed.

Registration holder and importer's name and address:

Pharmashalom Ltd., 21 Ha'Melacha St., Rosh Ha'Ayin 4809157.

Revised in August 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
107-66-20355