

Maalox® Sugar Free 400mg/400mg Chewable Tablets

aluminium hydroxide
magnesium hydroxide

Is this leaflet hard to see or read? Phone 01 403 5600 for help.

Read all of this leaflet carefully before you start taking this medicine.

- 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. It may harm them, even if their symptoms are the same as yours.
- If any side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Maalox is and what it is used for
2. Before you take Maalox
3. How to take Maalox
4. Possible side effects
5. How to store Maalox
6. Further information

1. WHAT MAALOX IS AND WHAT IT IS USED FOR

Maalox Sugar Free Chewable Tablets contain two different medicines. They are called Aluminium hydroxide and Magnesium hydroxide. They belong to a group of medicines called antacids. Maalox Sugar Free Chewable Tablets are used for:

- Heartburn or when your stomach has too much acid (indigestion)
- Lowering the amount of acid in your stomach or gut (intestine) when you have an ulcer.

Maalox works by lowering the amount of acid in your stomach.

2. BEFORE YOU USE MAALOX

Do not take Maalox if:

- You are allergic (hypersensitive) to Aluminium hydroxide or Magnesium hydroxide or any of the other ingredients in Maalox Tablets (see Section 6: Further Information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You are feeling very weak and have no energy (debilitated).
- You have kidney problems.
- You have low levels of phosphate (called 'hypophosphataemia'. This is shown up in blood tests.
- You have severe stomach pain.
- Your bowel is partially or fully blocked.

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

Warnings and precautions

Take special care with Maalox

Check with your doctor or pharmacist before taking this medicine if:

- You suffer from porphyria
- You suffer from diabetes

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Maalox.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. Maalox should not be taken at the same time as other medicines. This is because Maalox can affect the way other medicines work.

In particular, Maalox can affect the following medicines:

- Medicines used to treat the heart such as digoxin, quinidine, metoprolol, atenolol, rosuvastatin or propranolol
- Medicines used to treat anaemia such as iron salts
- Medicines used to treat dyspepsia such as ranitidine and cimetidine
- Medicines used to treat malaria such as chlorquine
- Medicines used to treat some bone disorders such as diphosphonates
- Medicines used to treat some allergic, inflammatory or autoimmune disorders such as glucocorticoids
- Medicines used to treat kidney disorders such as citrates
- Medicines used to treat tuberculosis such as ethambutol or isoniazid
- Medicines used to treat bacterial infections such as fluroquinolones or lincosamides
- Medicines used to treat infections such as ketoconazole, tetracyclines, cephalosporins such as cefpodoxime & cefdinir
- 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
- Non-steroidal anti-inflammatories such as diflunisal or indometacine
- Medicines used to treat thyroid problems such as levothyroxine
- Medicines used to treat arthritis such as penicillamine
- Vitamins

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 planning to breast-feed

You should not take Maalox during the first three months of pregnancy.

Important information about some of the ingredients of Maalox

Maalox Sugar Free Chewable Tablets contains 109.9mg of sorbitol (E420) and 632.62mg of Maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE MAALOX

Adults: 1-2 tablets chewed 4 times daily, taken 20 minutes to 1 hour after meals and at bedtime, or as directed by the physician. A maximum of 8 tablets in a 24 hour period should not be exceeded, nor should the maximum dose continue for more than 2 weeks except under the direction of the physician.

If you take more Maalox than you should

Talk to your doctor or go to a hospital straight away. Remember to take any medicine that is left with you so the doctor knows what you have taken.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Maalox can cause side effects, although not everybody gets them. **Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet:**

- Constipation
- Diarrhoea
- Allergic or anaphylactic reaction, signs include: red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing
- Hypophosphatemia, this may occur at high doses of the product or even at normal doses, especially in patients with low phosphorus diets or in infants less than 2 years
- Hypermagnesemia is an electrolyte disturbance where there is an abnormally elevated level of magnesium in the body
- Hyeraluminemia is an electrolyte disturbance where there is an abnormally elevated level of aluminium in the body

These side effects can happen, but are not common.

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MAALOX

Keep this medicine in a safe place where children cannot see or reach it.
Do not store above 25°C. Store in the original package to protect from moisture.
Do not use Maalox after the expiry date which is stated on the blister strip and carton after EXP. This expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Maalox contains

Each chewable tablet contains the active ingredients Aluminium Hydroxide 400 mg and Magnesium Hydroxide 400 mg. Other ingredients included in this medicine are sorbitol (E420) liquid (non-crystallizing), maltitol (E965), glycerol, saccharin sodium, magnesium stearate, lemon flavour and talc.

What Maalox looks like and contents of the pack

Maalox Sugar Free Chewable Tablets are white to yellow in colour with a lemon odour. They are available in blister strips of 20 or 40 tablets in a cardboard outer carton.

Marketing Authorisation Holder and Manufacturer

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