

MAALOX® 200mg/175mg per 5ml Oral Suspension

magnesium hydroxide

aluminium hydroxide

Is this leaflet hard to see or read?

Phone +353 1 4035600 for help

Read all of this leaflet carefully because it contains important information for you

This medicine is available without prescription. However, you still need to use Maalox Oral Suspension

carefully to get the best results from it.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

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- 1. What Maalox Oral Suspension is and what it is used for**
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1. What Maalox Oral Suspension is and what it is used for

Maalox Oral Suspension contains two different medicines.

They are called magnesium hydroxide and aluminium hydroxide. They belong to a group of medicines

called antacids. Maalox Oral Suspension is used for:

- The relief of indigestion (dyspepsia)

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

2. What you need to know before you take Maalox Oral Suspension

Do not take Maalox Oral Suspension if:

- You are allergic (hypersensitive) to aluminium hydroxide or magnesium hydroxide or any of the other ingredients in Maalox Oral Suspension (see Section 6: Contents of the pack and other 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
- 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 Oral Suspension.

Warnings and precautions

Take special care with Maalox Oral Suspension

Check with your doctor or pharmacist before taking your 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.

Other medicines and Maalox

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 Oral Suspension should not be taken at the same time as other medicines. This is because Maalox Oral Suspension can affect the way other medicines work.

Other medicines and magnesium hydroxide:

Some medicines may be affected by magnesium hydroxide or they may affect how well magnesium hydroxide will work. Tell your doctor or pharmacist if you are already taking: - salicylates

In particular, Maalox Oral Suspension can affect the following medicines:

- Medicines used to treat the heart such as digoxin, quinidine, metoprolol, atenolol or propranolol.
- Medicines used to treat anaemia such as iron salts.
- Medicines used to treat stomach ulcers and acidity such as ranitidine or cimetidine (H2 antagonists).
- Medicines used to treat malaria such as chloroquine.
- Medicines used to treat some bone disorders such as bisphosphonates.
- Medicines used to treat some allergic, inflammatory or abnormal immune reactions 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 infections such as fluoroquinolones, lincosamides, ketoconazole, cyclines, cephalosporins, (cefepodoxime & cefdinir), dolutegravir, elvitegravir, raltegravir potassium and 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 used to treat 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 pains and abnormal chemical reactions in the body such as penicillamine
- Medicines used to reduce cholesterol such as rosuvastatin
- Medicines used to treat cancer such as nilotinib, dasatinib monohydrate
- Medicines used to treat blood disorders such as eltrombopag olamine
- Medicines used to treat high blood pressure in the lungs (pulmonary hypertension) such as riociguat

As a precaution, staggering the administration times of any orally administered drugs and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

Pregnancy and breast-feeding

Use of Maalox Oral Suspension is not recommended during pregnancy.

Talk to your doctor about using Maalox Oral Suspension if:

- You are pregnant or planning to become pregnant.
- You are breast-feeding or planning to breast feed.

Important information about some of the ingredients of Maalox Oral Suspension

- Maalox Oral Suspension contains sorbitol (E420).

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine

- Maalox Oral Suspension contains 1.59mg of sodium per 5ml dose.

To be taken into consideration by patients on a controlled sodium diet.

3. How to take Maalox Oral Suspension

Taking this medicine

- Shake well before use
- Take this medicine by mouth
- If necessary, Maalox Oral Suspension may be taken with water or milk

Adults

- Take one to two 5ml spoonfuls
- Take 20 minutes to 1 hour after meals and at bedtime
- Alternatively, take as directed by your doctor

Do not take this medicine for prolonged periods as it may mask more serious diseases such as stomach ulcers or stomach cancer.

If the symptoms do not go away, talk to your doctor.

Children

Not recommended in children.

If you take more Maalox Oral Suspension than you should

The following effects may happen: diarrhoea, stomach pain or you may get a bloated feeling and cramping pain in the abdomen (stomach), be sick (vomit), have indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by an obstruction or blockage of the bowel (ileus).

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 Oral Suspension 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:

Uncommon:

- Constipation
- Diarrhoea

Very rare:

- Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment.

Not Known:

- Allergic or anaphylactic reactions, signs include; red and lumpy skin rash, swollen eyelids, face, lips,

mouth or tongue, itching, difficulty breathing or swallowing.

- Abdominal pain
- 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.
- Hyperaluminemia is an electrolyte disturbance in which there is an abnormally elevated level of aluminium in the body.

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 HPRAs Pharmacovigilance.

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Maalox Oral Suspension

Keep out of the sight and reach of children. Maalox should be disposed of within 6 months after first opening the bottle. Do not use Maalox Oral Suspension after the expiry date which is stated on the front label after EXP. The expiry date refers to the last day of that month. Do not store above 25°C. Medicines should not be disposed of via wastewater or house hold waste.

Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

6. Contents of the pack and other information

What Maalox Oral Suspension contains

- Each 5ml of suspension contains 200mg of magnesium hydroxide and 175mg of aluminium hydroxide, as the active ingredients.
- The other ingredients are: domiphen bromide, citric acid (monohydrate), saccharin sodium, sorbitol 70% liquid non crystallising (E420), hydrogen peroxide, mannitol, hydrochloric acid, peppermint oil and purified water.

What Maalox Oral Suspension looks like and contents of the pack

Maalox Oral Suspension is a white, peppermint flavoured suspension and is available in 60ml, 250ml and 355ml plastic bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.
This leaflet was last revised in February 2022.