

MAALOX® Plus 200mg/175mg/25mg per 5ml

Oral Suspension

magnesium hydroxide

aluminium hydroxide

simethicone

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 Plus 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.

In this leaflet:

1. What Maalox Plus Oral Suspension is and what it is used for
2. What you need to know before you take Maalox Plus Oral Suspension
3. How to take Maalox Plus Oral Suspension
4. Possible side effects
5. How to store Maalox Plus Oral Suspension
6. Contents of the pack and other information

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

Maalox Plus Oral Suspension contains three different medicines:

- The first two medicines are called magnesium hydroxide and aluminium hydroxide. They belong to a group of medicines called antacids.
- The other medicine is called simeticone. It belongs to a group of medicines called anti-foaming agents.

Maalox Plus Oral Suspension is used for:

- The relief of indigestion (dyspepsia)
- Heartburn
- Wind (flatulence)

Maalox Plus Oral Suspension works by lowering the amount of acid in your stomach. The anti-foaming agents in Maalox Plus Oral Suspension help to remove gas from your stomach.

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

Do not take Maalox Plus Oral Suspension if:

- You are allergic (hypersensitive) to magnesium hydroxide, aluminium hydroxide, simeticone or any of the other ingredients in Maalox Plus 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 disease
 - 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 Plus Oral Suspension.

Warnings and precautions

Take special care with Maalox Plus 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 Plus Oral Suspension.

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 Plus Oral Suspension can affect the way other medicines work.

Talk to your doctor or pharmacist before taking Maalox Plus Oral Suspension if you are taking aspirin or drugs containing acetylsalicylic acid or tetracycline containing antibiotics or any tetracycline salts.

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 Plus 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 Plus Oral Suspension is not recommended during pregnancy.

Talk to your doctor about using Maalox Plus Oral Suspension if:

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

Maalox Plus 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 Plus Oral Suspension contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially "sodium-free".

Maalox Plus Oral Suspension contains sulphur dioxide (E220)

May rarely cause hypersensitivity reactions and bronchospasm.

Maalox Plus Oral Suspension contains ethanol

Maalox Plus Oral Suspension contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml.

3. How to take Maalox Plus Oral Suspension

Taking this medicine

- Shake well before use
- Take this medicine by mouth

Adults

- Take one to two 5ml spoonfuls 4 times each day
- 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 Plus 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 Plus 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:

In Ireland:

HPRA Pharmacovigilance

Website: www.hpra.ie

In Malta:

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Maalox Plus Oral Suspension

Keep out of the sight and reach of children. Maalox Plus should be disposed of within 6 months after first opening the bottle. Do not use Maalox Plus 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. Store below 30°C. Do not freeze. Keep bottle tightly closed. Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Maalox Plus Oral Suspension contains

- Each bottle contains the following active substances in each 5 ml of suspension: 200mg of magnesium hydroxide, 175mg aluminium hydroxide and 25mg simeticone.
- The other ingredients are: domiphen bromide, methyl-cellulose, microcrystalline cellulose, carmellose sodium, hypolose, citric acid monohydrate, saccharin sodium, sorbitol 70% liquid non crystallising (E420), hydrogen peroxide, natural lemon concentrate (contains ethanol), swiss crème flavour (contains ethanol and sulphur dioxide (E220)) and purified water.

What Maalox Plus Oral Suspension looks like and contents of the pack

Maalox Plus Oral Suspension is a white suspension with the odour and taste of lemon and is available in a plastic bottle. Maalox Plus Oral Suspension is available in 250ml and 355ml plastic bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

In Ireland:

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
France.

In Malta:

Opella Healthcare France SAS
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Manufacturer

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For any information about this medicine, please contact the distributor & local representative of the Marketing Authorisation Holder: Clonmel Healthcare Ltd,
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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.

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