

PACKAGE LEAFLET: INFORMATION FOR THE USER

Maalox[®] Plus Tablets

Dried Aluminium Hydroxide Gel 200mg

Magnesium Hydroxide 200mg

Simeticone 25mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

This medicine is available without prescription. However, you still need to use Maalox Plus Tablets 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
- You must contact a doctor if your symptoms worsen or do not improve
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Maalox Plus Tablets and what they are used for
2. What you need to know before you take Maalox Plus Tablets
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1. What Maalox Plus Tablets are and what they are used for

Maalox Plus Tablets contain three different medicines

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

Maalox Plus Tablets is used for:

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

Maalox Plus tablets work by lowering the amount of acid in your stomach. The anti-foaming agent in Maalox Plus Tablets helps remove gas from your stomach.

2. What you need to know before you take Maalox Plus Tablets

Do not take Maalox Plus Tablets if:

- You are allergic (hypersensitive) to dried aluminium hydroxide gel, magnesium hydroxide, simethicone or any of the other ingredients in Maalox Plus tablets (listed

in section 6). 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/kidney failure

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 Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Maalox Plus Tablets if:

- You are on a low-phosphorus diet

Other medicines and Maalox Plus Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines.

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

In particular:

- Medicines used to treat the heart such as digoxin, quinidine, metoprolol, atenolol and 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, isoniazid
- Medicines used to treat infections such as fluoroquinolones, lincosamides, ketoconazole, cyclines including tetracyclines, cephalosporins (cefpodoxime & 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 phenothiazine, 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
- Salicylates including aspirin

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

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

Important information about some of the ingredients of Maalox Plus Tablets

Maalox Plus Tablets contain anhydrous glucose, sucrose and sorbitol(E420). This product may be harmful to teeth. If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3. How to take Maalox Plus Tablets

Taking this medicine

- Take this medicine by mouth
- Chew the tablets well by swallowing

Adults including the elderly

- Take one or two tablets 4 times a day
- Take 20 minutes to one hour after meals and at bedtime or as required

Children

Maalox Plus Tablets are not recommended for children.

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

If you take more Maalox Plus Tablets 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 that the doctor knows what you have taken.

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)

4. Possible side effects

Like all medicines, Maalox Plus Tablets can cause side effects, although not everybody gets them.

Stop taking Maalox Plus Tablets and see a doctor or go to a hospital straight away if:

Not known (frequency cannot be estimated from the available data)

- You have a red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching, difficulty breathing or swallowing. This can be an allergic reaction.

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 (may affect up to 1 in 100 people)

- Constipation
- Diarrhoea

Very rare (may affect up to 1 to 10,000 people)

- Hypermagnesia, including observations after prolonged administration to patients with renal impairment.

Not known (frequency cannot be estimated from the available data)

- Hypophosphatemia, this may occur at high doses of the product or even at normal doses especially in patients with low phosphorus diets
- Hyperaluminemia is an electrolyte disturbance in which there is an abnormally elevated level of aluminium in the body
- Abdominal pain

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.

United Kingdom

You can also report side effects directly via the Yellow Cards scheme at www.mhra.gov.uk/yellowcard or search for MHRA yellow card in the Google Play or Apple app stores.

Malta

You can also report side effects directly to ADR reporting: 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 Tablets

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Maalox Plus Tablets after the expiry date which is stated on the carton and foil after EXP. The expiry date refers to the last day of that month.

Store below 25° C.

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 protect the environment.

6. Contents of the pack and other information

What Maalox Plus Tablets contain

- Each tablet contains: 200mg of dried aluminium hydroxide gel, 200mg of magnesium hydroxide and 25mg of simethicone.
- The other ingredients are: swiss cream flavour, lemon flavour, magnesium stearate, talc, anhydrous citric acid, anhydrous glucose, saccharin sodium, sorbitol (E420), sorbitol liquid non-crystallising (E420), iron oxide yellow (E172), pregelatinized starch (maize starch), maize starch, sucrose and mannitol (E421)

What Maalox Plus Tablets look like and contents of the pack

Maalox Plus Tablets are white and yellow with 'Maalox' embossed on one side. They taste of lemon/cream.

Maalox Plus Tablets are made in blister packs containing 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 72, 80, 84, 90, 96 and 100 tablets or tubes containing 12, 24, 36, 48, 72 and 144 tablets. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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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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