

PACKAGE LEAFLET: INFORMATION FOR THE USER

MAALOX® Plus Suspension

Aluminium hydroxide 175mg/5 ml
Magnesium hydroxide 200 mg/5 ml
Simeticone 25 mg/5 ml

sanofi

**Is this leaflet hard to see or read?
Phone 0800 035 2525 for help**



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

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



Maalox Plus contains three different medicines:

- The first two medicines are called aluminium hydroxide and magnesium 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 is used for:

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

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

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



Do not take Maalox Plus if:

X You are allergic (hypersensitive) to aluminium hydroxide, magnesium hydroxide, simeticone or any of the other ingredients in Maalox Plus (listed in section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

X You are feeling very weak and have no energy (debilitated)

X You have kidney disease / kidney failure

X 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.

Warnings and precautions

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

- You are on a low-phosphorous diet
- You are suffering from porphyria and are undergoing haemodialysis.

Children

In small children use of magnesium hydroxide may cause hypermagnesemia particularly if they have renal impairment or dehydration.



Other medicines and Maalox Plus

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 anemia 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 (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 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 and 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.

Turn
Over

- You are breast-feeding or planning to breast-feed

Important information about some of the ingredients of Maalox Plus

This medicine contains 224 mg sorbitol in each 5ml unit which is equivalent to 44.8mg/ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to 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 you (or your child) take or receive this medicine.

Maalox Suspension contains less than 1 mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium free'.

3. How to take Maalox Plus

Taking this medicine

- Shake well before use
- Take this medicine by mouth

Adults including the elderly

- Take one to two 5 ml spoonfuls 4 times each day
- Take 20 minutes to 1 hour after meals and at bedtime
- Alternatively, take as directed by your doctor

Children aged 12 to 18 years

- Give your child one to two 5 ml spoonfuls 4 times each day
- Give this medicine 20 minutes to 1 hour after meals and at bedtime
- Alternatively, give as directed by your doctor

Children aged 5 to 12 years

- Give your child a maximum of one 5 ml spoonful 3 to 4 times each day
- Give this medicine 20 minutes to 1 hour after meals or at bedtime
- Alternatively, give as directed by your doctor

Children 2 to 5 years old

- Do not give your child more than one 5 ml spoonful three times each day
 - Give this medicine 20 minutes to 1 hour after meals and at bedtime
 - Alternatively, give as directed by your doctor
- If the symptoms do not go away, talk to your doctor.

If you take more Maalox Plus 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

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).

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

Stop taking Maalox Plus 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 could 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 in 10,000 people)

- Hypermagnesemia, 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.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Maalox Plus

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

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

Do not refrigerate or freeze. Store below 30°C.

Maalox Plus should be disposed of 6 months after opening the bottle.

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 contains

- Each bottle contains the following active substances in each 5ml of suspension: 175mg of aluminium hydroxide, 200mg of magnesium hydroxide and 25mg of simeticone
- The other ingredients are: domiphen bromide, microcrystalline cellulose, methylcellulose, hydroxypropylcellulose, hydrogen peroxide, citric acid monohydrate, sodium saccharin, sorbitol (E420), carmellose sodium, lemon flavour, swiss cream flavour and water

What Maalox Plus looks like and contents of the pack

Maalox Plus is a white suspension, homogenous after shaking and is available in a plastic bottle. Each bottle contains 250ml or 355ml with polypropylene closure.

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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