

MAALOX[®] PLUS SUSPENSION

Magnesium Hydroxide/Aluminium Hydroxide/Simethicone (200mg/225mg/25mg per 5ml)

What is in this leaflet

1. What Maalox[®] Plus is used for
2. How Maalox[®] Plus works
3. Before you use Maalox[®] Plus
4. How to use Maalox[®] Plus
5. While you are using it
6. Side effects
7. Storage and Disposal of Maalox[®] Plus
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Maalox[®] Plus is used for

To provide symptomatic relief of hyperacidity plus alleviation of gas symptoms associated with stomach or intestinal ulcer, gastric inflammation, heartburn, or gas pain after operation. To provide symptomatic relief of abdominal bloating.

How Maalox[®] Plus works

Maalox[®] Plus is a balanced mixture of two antacids, aluminium hydroxide is a slow antacid and magnesium hydroxide is a quick acting one. Simethicone is a gastric defoaming agent, used to combine lots of small bubbles into larger bubbles, which can be expelled more easily.

Before you use Maalox[®] Plus

-When you must not use it

- Hypersensitivity to active substance or any of the ingredients; signs of an allergic reaction are skin rash, swelling of the lips, tongue, face and throat, and breathing problems
- Porphyria
- Serious kidney problems
- Children
- Cachexia

-Before you start to use it

Maalox[®] Plus Suspension is not recommended for children. Inform your doctor if you have kidney disease.

Pregnancy

Maalox[®] Plus should only be used when absolutely necessary. Consult your doctor to make an evaluation of the expected benefit for the mother in relation to the risk for the fetus or baby.

Lactation

Maalox[®] Plus is considered compatible with breast-feeding.

-Taking other medicines

Tell your doctor if you are taking, have recently taken or might take any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by magnesium hydroxide or may affect how it works.

This medicine can interfere with the effects of:

- medicines used to control stomach acidity (H₂ antagonists);
- medicines for the heart and blood pressure (atenolol, digoxin, metoprolol, and propranolol);
- medicines used to treat anaemia, such as iron salts
- anti-infective medicines (cefdinir, cefpodoxime, tetracyclines, ethambutol, fluoroquinolones, isoniazid, lincosamides, penicillamines, ketoconazole),
- dolutegravir, elvitegravir, raltegravir
- potassium, and antiviral treatments in combination with tenofovir
- alafenamide fumarate/ emtricitabine/ bictegravir sodium, rilpivirine;
- antimalarial medicines (chloroquine);
- anti-inflammatory medicines (diflunisal, glucocorticoids, indomethacin);
- medicines used to treat teeth, such as sodium fluoride
- medicines for bone diseases (bisphosphonates);
- medicines for the thyroid (levothyroxine);
- medicines against schizophrenia (phenothiazine neuroleptics);
- medicines to lower cholesterol (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 pressure in the lungs (pulmonary hypertension), such as riociguat.

Wait at least two hours (4 hours for fluoroquinolones), before taking

Maalox[®] Plus to avoid interaction with the other medicines.

You must also tell your doctor or pharmacist if you are taking:

- medicines containing polystyrene sulfonate (Kayexalate), due to the risk of metabolic and intestinal problems.
- medicines containing aluminium hydroxide and citrates, due to the risk of increased aluminium in the blood.
- quinidine (medicine for the heart) due to the risk of increased quinidine levels.
- salicylates.

How to use Maalox[®] Plus

-How much to use

Two to four tea spoonsful, four times a day.

Do not take more than 16 teaspoonsful in a 24-hour period.

-When to use it

Take twenty minutes to one hour after meals and at bedtime, or as directed by your doctor.

-How long to use it

Use Maalox[®] Suspension for the duration as your doctor recommends. Do not use the maximum dosage for more than two weeks.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for missed dose.

-If you use too much (overdose)

If you take too much than you should, tell your doctor or go to your nearest hospital casualty department straight away. Remember to take the pack with you.

If you take high doses of this medicine, the following may occur:

- diarrhea, abdominal pain and vomiting.
- worsening of intestinal problems if you have constipation or are elderly.

While you are using it**-Things you must do**

Use your medicine exactly as your doctor or pharmacist has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Maalox® Plus.

-Things you must not do

Do not utilize after the expiry date which is stated on the box after "EXP". The expiry date refers to the last day of that month.

-Things to be careful of

Tell your doctor immediately if you become pregnant while taking this medication.

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

- if you have intestinal problems or constipation, if you have non-serious kidney problems or if you are elderly, as this medicine may worsen intestinal problems.
- if you are following a low-phosphorus diet, if you have low levels of phosphates in the blood (hypophosphatemia) or if you are receiving long-term treatment. This medicine reduces phosphate levels in the blood and can cause bone problems.
- If you are taking high doses of this medicine or if you are subject to diarrhea, pay careful attention because this medicine can cause diarrhea.

Contains approximately 0.174 mg sodium per teaspoonful; hence that is to say essentially sodium-free. Contains 224 mg sorbitol per teaspoonful; patients with heredity fructose intolerance (HFT) shouldn't take this product

Side Effect**Uncommon side effects:**

Diarrhea and constipation

Very rare side effects:

Hypermagnesemia

Not known frequency side effects:

- excessive reaction of the body to foreign substances (hypersensitivity reaction), a skin rash that may be itchy, characterized by swelling on the skin (hives), itching.

- changes in aluminium and phosphate levels in the blood which can cause bone problems.
- abdominal pain

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Maalox® Plus**-Storage**

Store below 30°C

Keep out of reach of children.

Use the medicine within 6 months after first opening.

-Disposal

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.

Product Description**-What it looks like**

White suspension with odour and taste of lemon.

-Ingredients:**- Active ingredients:**

Magnesium Hydroxide; Dried Aluminium Hydroxide gel (equivalent to aluminium hydroxide); Simethicone

- Inactive ingredients:

Citric acid monohydrate, sorbitol liquid, hydroxypropylcellulose, methylcellulose, hydrogen peroxide, lemon flavor, domiphen bromide, Swiss cream flavor, saccharin sodium, microcrystalline cellulose+carmellose sodium.

-MAL number(s):

MAL19940522X

Manufacturer

Opella Healthcare Italy S.r.l Viale Europa 11
21040 Origgio- (Va)
ITALY.

Product Registration Holder

DKSH Malaysia Sdn Bhd
B-11-01, The Ascent, Paradigm
No. 1, Jalan SS7/26A, Kelana Jaya

47301, Petaling Jaya,
Selangor Darul Ehsan,
Malaysia

Date of revision

02/03/2023

Serial Number

NPRA(R2/2)230517/1068