

MAALOX[®] ORAL SUSPENSION IN SACHET

Magnesium Hydroxide / Aluminium Hydroxide (400mg / 460mg)

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What Maalox[®] is used for

The name of your medicine is Maalox[®] Oral Suspension in sachets (called Maalox[®] throughout this leaflet).

Maalox[®] is used for:

- Stomach ulcer
- Inflammation or irritation of the stomach
- Inflammation of esophagus (esophagus is the tube that sends food from your throat down to your stomach)
- Gastric hyperacidity (excess production of stomach acid)
- Heartburn
- Hiatal hernia (the stomach pushes through the opening in the diaphragm where the esophagus and stomach meet)

How Maalox[®] works

Maalox[®] contains two different medicines. They are called aluminium hydroxide and magnesium hydroxide. They belong to a group of medicines called antacids. Maalox[®] works by lowering the amount of acid in your stomach.

Before you use Maalox[®]

-When you must not use it

Do not take Maalox[®] if:

- You are allergic (hypersensitive) to any ingredients of Maalox[®]
- Signs of an allergic reaction include: a rash, swallowing or

breathing problems, swelling of your lips, face, throat or tongue

- You have porphyria (a rare hereditary blood metabolism disorder)
- You have severe kidney problems, as the medicinal products contains magnesium
- Your body is severely emaciated (cachexia)

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[®].

-Before you start to use it

Take special care with Maalox[®] and contact your doctor 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
- 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
- You are taking high doses of this medicine or if you are susceptible to diarrhoea, exercise caution because this medicine can cause diarrhoea (see section "Side effects")

-Children and adolescents

Use of magnesium hydroxide in small children, particularly those with kidney impairment or dehydration, may result in hypermagnesemia.

-Taking other medicines

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.

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

This medicine may interact with

other medicines. If you are taking other medicines, you must wait at least 2 hours before taking Maalox[®] and at least 4 hours if you are taking certain antibiotics (fluoroquinolones).

This medicine may interfere with the effects of:

- Medicines used to treat the heart and blood pressure such as digoxin, metoprolol, atenolol or propranolol.
- Anti-infective medicines such as cefdinir, cefpodoxime, tetracyclines, ethambutol, fluoroquinolones, isoniazid, lincosamides, penicillamines, ketoconazole.
- Medicines used to treat malaria such as chloroquine.
- Medicines used to treat some bone disorders such as bisphosphonates.
- Medicines for the thyroid (levothyroxine)
- Medicines used to treat some allergic, inflammatory or autoimmune disorders such as dexamethasone, prednisolone, and fexofenadine
- Medicines against schizophrenia such as phenothiazines neuroleptics.
- Medicines used to inhibit the production of gastric acid such as lansoprazole
- Anti-inflammatories drugs such as indomethacin, diflunisal
- Medicines to lower cholesterol (rosuvastatin);
- Medicines containing iron or sodium fluoride.
- Medicines used to decrease the production of stomach acid such as H2 antihistamine

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.

Pregnancy and breast-feeding

This medicine can only be taken if your doctor has considered it necessary and under his/her supervision.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

MAALOX® contains:

- approximately 3 g of **sucrose** per sachet. This should be taken into account in patients with diabetes mellitus (if more than one sachet is taken per day). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 140 mg **sorbitol** per sachet. Sorbitol is a source of fructose. If your doctor has told you that 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 take or receive this medicine.
- less than 1 mmol **sodium** (23 mg) per dose, that is to say essentially 'sodium-free'.

How to use Maalox®

Always take Maalox® exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Drink the suspension as is: do not dilute.
- Knead the sachets carefully before opening.

-How much to use

Adults (aged 15 years and above)

- 1 to 2 sachets per intake when heartburn or acid regurgitation occurs.
- Maalox® oral suspension may be taken 20 minutes to one hour after meals and at bedtime or as required.

- Number of doses per day: 6
- No more than 12 sachets should be taken per day.

Maalox® is not recommended for children less than 15 years of age.

-When to use it

Take Maalox® at about the same time each day; taken twenty minutes to one hour after meals and at bedtime, unless your doctor tells you otherwise.

-How long to use it

Do not use Maalox® frequently or for a prolonged period without consulting the doctor.

-If you forget to use it

- Do not take a double dose to make up for a forgotten dose.
- If you have any further questions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

Immediately telephone your doctor or go to the nearest hospital emergency department, if you think that you or anyone else may have taken too much Maalox®. Do this even if there are no signs of discomfort or poisoning. Take the medicine pack with you. You may need urgent medical attention.

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

- diarrhoea, abdominal pain and vomiting;
- worsening of intestinal problems if you have constipation, have non-serious kidney problems or are elderly.

While you are using it

-Things you must do

- Tell all the doctors and pharmacists who are treating you that you are taking Maalox®.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Maalox®.
- If the symptoms persist after 10 days of treatment or worsen, the cause should be investigated and the treatment should be reassessed by your doctor.

-Things you must not do

- Do not give this medicine to

anyone else, even if they have the same condition as you.

- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Maalox®, or change the dosage, without checking with your doctor.

-Things to be careful of

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

Side Effect

Like all medicines, Maalox® can cause side effects, although not everyone gets them.

Stop taking Maalox® and talk to your doctor immediately or go to the nearest hospital if you

experience: difficulty breathing or swallowing, swelling of the face, hands and feet, eyes, lips and/or tongue, skin rash, itching, hives and dizziness, as these can be symptoms of severe allergic reactions (angioedema and anaphylactic reaction).

When using this medicine, the following side effects may occur:

Uncommon (may affect up to 1 in 100 people):

- constipation (stipsis) or diarrhoea.

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

- hypermagnesemia, which has been observed with prolonged use in patients with kidney impairment.

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

- excessive reaction of the body to foreign substances (hypersensitivity

reaction, including severe ones), 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
np.ra.gov.my [Consumers →
Reporting Side Effects to
Medicines (ConSERF) or
Vaccines (AEFI)]

Storage and Disposal of

Maalox[®] If you have any
queries about any aspect of
your medicine, or any
questions regarding the
information in this leaflet,
discuss them with your doctor or
pharmacist.

-Storage

- Where children cannot see or reach it.
- Do not use Maalox[®] after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
- Store below 30°C.

-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

Maalox[®], oral suspension is
white to faintly yellow,
homogeneous suspension. It is
packed into sachets of 4.3ml
equivalent to 6g of suspension.

-Ingredients:

Active ingredients for one sachet:

- Aluminum oxide 230mg
(As hydrated aluminum oxide
460mg)
- Magnesium hydroxide 400mg

Inactive ingredients for one
sachet: Sucrose solution 64%,
Sorbitol Liquid (non-
crystallizing), xanthan gum,
guar, natural lemon lime flavor,
sodium chloride and hydrogen
peroxide solution 30%

MAL Numbers:

MAL12035009X

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
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Petaling JayaSelangor Darul
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