

PACKAGE LEAFLET: INFORMATION FOR THE USER

MAALOX® 175mg/200mg Oral Suspension

Aluminium hydroxide 175mg/5 ml

Magnesium hydroxide 200mg/5 ml

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. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

You must talk to a doctor if you do not feel better or if you feel worse

What is in this leaflet:

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

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

Maalox Suspension contains two different medicines. They are called aluminium hydroxide and magnesium hydroxide. They belong to a group of medicines called antacids.

Maalox Suspension is used for:

- Heartburn or when your stomach has too much acid (indigestion)
- Inflammation of the stomach (gastritis), and
- When prescribed by a doctor it may also be used for lowering the amount of acid in your stomach or gut (intestine) when you have an ulcer

Maalox Suspension works by lowering the amount of acid in your stomach.

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

Do not take Maalox Suspension if:

- You are allergic to aluminium hydroxide or magnesium hydroxide or any of the other ingredients in Maalox Suspension (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. Long term exposure to high doses of Maalox Suspension can lead to dementia.

- You have severe stomach pain
- Your bowel is partially or fully blocked

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 Suspension.

Warnings and precautions

Take special care with Maalox Suspension. Check with your doctor or pharmacist before taking this medicine if:

You are on a low-phosphorous diet

Other medicines and Maalox Suspension

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 Suspension should not be taken at the same time as other medicines. This is because some medicines may be affected by Maalox Suspension or they may affect how well Maalox Suspension 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 and hydroxychloroquine
- Medicines used to treat some bone disorders such as bisphosphonates
- Medicines used to treat some allergic, inflammatory or abnormal immune reactions such as glucocorticoids
- Medicine used to treat kidney disorders such as citrates
- Medicines used to treat tuberculosis such as ethambutol, isoniazid
- Medicines used to treat infections such as tetracycline, ciprofloxacin, rifampicin, 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 chlorpromazine, 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
- Salicylates
- Vitamins

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 should not take Maalox Suspension during the first three months of pregnancy
- You are breast-feeding or planning to breast-feed

Maalox Suspension contains sorbitol (E420).

This medicine contains 50 mg sorbitol in each 5ml which is equivalent to 10mg/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 (23 mg) per 5 ml dose, i.e. essentially 'sodium free'.

3. How to take Maalox Suspension

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Shake well before use to ensure the product is mixed properly
- Take this medicine by mouth
- If necessary, Maalox Suspension may be taken with water or milk

Adults, the elderly and children aged 14 years or older

- Take two to four 5ml teaspoonfuls
- Take 20 minutes to 1 hour after meals and at bedtime
- Alternatively, take as directed by your doctor

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

Children less than 14 years old

- Maalox Suspension is not recommended for children less than 14 years of age

If you take more Maalox Suspension 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.

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 Suspension can cause side effects, although not everybody gets them.

Stop taking Maalox Suspension 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 and 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 is an electrolyte disturbance in which there is an abnormally low level of phosphate in the body. This may occur at high doses of the product or even at normal doses especially in patients with low phosphorous diets
- Abdominal pain
- 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 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 Suspension

Keep this medicine out of the sight and reach of children.

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

Discard any medicine remaining 6 months after opening the bottle.

Store below 25°C.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Maalox Suspension contains

Each 5ml of suspension contains 175mg of aluminium hydroxide and 200mg of magnesium hydroxide as the active ingredients.

The other ingredients are: hydrochloric acid, citric acid monohydrate, peppermint oil, mannitol (E421), domiphen bromide, saccharin sodium, sorbitol liquid (E420), hydrogen peroxide and purified water.

What Maalox Suspension looks like and contents of the pack

Maalox Suspension is a white, mint flavoured suspension and is available in a 250ml polyethylene terephthalate (PET) bottle, with a polypropylene (PP) closure and polyethylene (PE/LDPE) liner.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Sanofi
410 Thames Valley Park Drive
Reading
Berkshire
RG6 1PT
UK

Tel: 0800 035 2525

email: uk-medicalinformation@sanofi.com

Manufacturer:

Opella Healthcare Italy S.r.l.
viale Europa, 11
21040 Origgio (Va)
Italy

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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