

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986**

This medicine is dispensed without a doctor's prescription

## **Maalox Plus Suspension**

### **Active ingredients**

Each teaspoon (5 ml) of suspension contains:

- 175 mg aluminium hydroxide
- 200 mg magnesium hydroxide
- 25 mg simethicone

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Call your doctor if your symptoms of illness get worse or do not improve.

### **1. What is this medicine intended for?**

Antacid, antiflatulent and relief of sensation of heartburn.

#### **Therapeutic group:**

Aluminium hydroxide and magnesium hydroxide: antacids.  
Simethicone: anti-flatulent.

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

### **2. Before using this medicine**

#### **Do not use this medicine if you:**

- are allergic (sensitive) to aluminium hydroxide, magnesium hydroxide, simethicone, or any of the other ingredients in this medicine (see section 6). Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- are feeling very weak and have no energy
- have kidney disease/kidney failure
- have low levels of phosphate in your blood (hypophosphataemia). This condition shows in blood tests.

Do not take this medicine if any of the above conditions apply to you. If you are not sure, talk to your doctor or pharmacist before taking Maalox Plus Suspension.

#### **Special warnings about using this medicine**

Talk to your doctor or pharmacist before starting treatment if:

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

#### **Children and adolescents**

This medicine is not intended for children under 6 years old.

In small children use of magnesium hydroxide may cause hypermagnesaemia (high level of magnesium in the blood), particularly if they have kidney problems or are dehydrated.

### **Interactions with other medicines**

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.**

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

### **Particularly tell your doctor or pharmacist if you are taking:**

- heart medicines, such as digoxin, quinidine, metoprolol, atenolol and propranolol
- medicines for anaemia, such as iron salts
- medicines used to treat stomach ulcers and acidity, such as ranitidine or cimetidine (H2 antagonists)
- medicines for malaria, such as chloroquine, hydroxychloroquine
- medicines for some bone disorders, such as bisphosphonates
- medicines used to treat some allergic, inflammatory or abnormal immune reactions, such as glucocorticoids
- medicines for kidney disorders, such as citrates
- medicines for tuberculosis, such as ethambutol, isoniazid
- medicines used to treat infections, such as fluoroquinolones, lincosamides, ketoconazole, cyclines including tetracyclines, cephalosporins (cefepodoxime and cefdinir), dolutegravir, elvitegravir, raltegravir potassium, rifampicin, antiviral combination treatment with tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, rilpivirine
- medicines used to treat mental illness (psychosis), such as chlorpromazine, phenothiazine neuroleptics
- medicines used to treat increased amounts of potassium in the body, such as polystyrene sulfonate
- medicines for 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 pain and abnormal chemical reactions in the body, such as penicillamine
- medicines used to reduce cholesterol, such as rosuvastatin
- medicines for cancer, such as nilotinib, dasatinib monohydrate
- medicines used to treat blood disorders, such as eltrombopag olamine
- medicines for high blood pressure in the lungs (pulmonary hypertension), such as riociguat
- salicylates including aspirin
- vitamins

As a precaution, allow at least 2 hours (4 hours for the fluoroquinolones) between any medicine taken by mouth and the antacid.

### **Using this medicine and food**

The suspension can be taken with water or milk.

Drink the suspension 20 minutes to one hour after a meal.

### **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 plan to breast-feed

### **Important information about some of this medicine's ingredients**

**Maalox Plus Suspension contains sorbitol.** Each 5 ml dose of this medicine contains 224 mg sorbitol. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to or the inability to digest 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 using this medicine.

Maalox Plus Suspension contains less than 1 mmol sodium (23mg) per 5 ml dose, so it is considered "sodium free".

### **3. How to use this medicine?**

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

This medicine is taken by mouth; shake well before use. If necessary, this medicine can be taken with water or milk.

Use the measuring spoon or cup to measure the correct amount of medicine. Do not use a household spoon to measure the amount of medicine. Household spoons vary in size and you may not get the correct amount of medicine.

**Unless directed otherwise by your doctor, the recommended dosage is usually:**

**Adults, the elderly, and adolescents aged 12–18:**

5–10 ml 4 times a day, 20 minutes to one hour after a meal. Take the suspension at bed time, too.

**Children aged 6–12 years:**

5 ml 3–4 times a day, 20 minutes to one hour after meals. Take the suspension at bed time, too.

**This medicine is not intended for children under 6 years old.**

**Do not exceed the recommended dose.**

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

Do not take this medicine for longer than two weeks unless directed by your doctor.

**If you have accidentally taken an overdose**, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**

**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

### **4. Side effects**

As with any medicine, using Maalox Plus Suspension may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following effects may happen: diarrhoea, stomach pain or a bloated feeling and cramping pain in the abdomen (stomach), vomiting, indigestion, heartburn, upset stomach, constipation, loss of appetite, dry mouth. This could be caused by blockage of the bowel (ileus).

**Stop taking this medicine and see a doctor or go to a hospital straight away if:**

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. The frequency of this side effect is unknown.

**Talk to your doctor or pharmacist if any of the following side effects get worse or last longer than a few days:**

**Uncommon side effects** (affect up to 1 in 100 users):

- constipation
- diarrhoea

**Very rare side effects** (affect up to 1 in 10,000 users):

hypermagnesaemia (high levels of magnesium in the blood), was also observed in patients with impaired kidney function who received prolonged treatment with this medicine.

**Side effects of unknown frequency** (side effects whose frequency has not been established yet):

- hypophosphataemia (low level of phosphate in the blood), which may occur with prolonged use or high doses of the product or even at normal doses especially in patients who are on low phosphorus diets
- hyperaluminaemia (abnormally elevated level of aluminium in the blood)
- abdominal pain

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

## 5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

### Storage conditions

Store below 30°C. Do not freeze. Keep the bottle tightly closed.

Use within 6 months of first opening.

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 protect the environment.

## 6. Additional information

**In addition to the active ingredients, this medicine also contains:**

sorbitol liquid 70% (non-crystallizing), hydroxypropylcellulose, microcrystalline cellulose + carmellose sodium, lemon flavour, citric acid monohydrate, hydrogen peroxide 30%, Swiss cream flavour, methylcellulose, sodium saccharin, domiphen bromide, purified water.

**What the medicine looks like and contents of the pack:**

a white suspension, homogenous after shaking, available in a 355 ml plastic bottle.

This pack contains a measuring cup.

**Registration holder and importer's name and address:**

Pharmashalom Ltd., 21 Ha'Melacha St., Rosh Ha'Ayin 4809157.

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Registration number of the medicine in the Ministry of Health's National Drug Registry:  
107-65-20354