

magnesium hydroxide, aluminum hydroxide and dimethicone (oral suspension)  
magnesium hydroxide, dried aluminum hydroxide gel and dimethicone (chewable tablets)

**PRIOR TO THE USE READ CAREFULLY ALL THE INFORMATION CONTAINED IN THE PRODUCT INFORMATION LEAFLET**

This is a SELF-MEDICATION drug, which you could use to treat mild and transient disorders, which may be easily identified and resolved without recurring to the aid of a physician.

Therefore, it may be bought without medical prescription, but should be used correctly to assure its efficacy and reduce any adverse effects.

- for better information and advises, consult the pharmacist
- consult the physician if the disorder is not resolved after a short period of treatment.

**NAME OF THE MEDICINAL PRODUCT:**

MAALOX<sup>®</sup> PLUS oral suspension  
MAALOX<sup>®</sup> PLUS chewable tablets

**COMPOSITION:**

**100 ml of suspension contain:**

*Active ingredients:*

Magnesium Hydroxide	3.65 g
Aluminum Hydroxide	3.25 g
Dimethicone	0.50 g

*Excipients:*

Methyl cellulose, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Carboxymethyl cellulose, Hydroxypropyl cellulose, Citric acid, Sodium saccharin, Sorbitol solution 70%, Lemon flavor, Swiss cream flavor, Purified water.

**Each chewable tablet contains:**

*Active ingredients:*

Magnesium Hydroxide	200 mg
Dried Aluminum Hydroxide gel	200 mg
Dimethicone	25 mg

*Excipients:*

Maize starch, Citric acid, Pregelatinized starch, Glucose, Mannitol, Saccharose, Sorbitol, Sorbitol solution 70%, Talc, Magnesium stearate, Sodium saccharin, Lemon flavor, Swiss cream flavor, E 172.

**HOW SUPPLIED:**

MAALOX<sup>®</sup> PLUS is available in the form of chewable tablets and suspension, both for oral use.

The packs contain:

- 30 tablets;
- bottle of 200 ml of suspension;
- 15 sachets, each of 15 ml of suspension.

**WHAT MAALOX<sup>®</sup> PLUS IS:**

MAALOX<sup>®</sup> PLUS is an antacid combined with an antimeiotic agent.

It is active against gastric pyrosis and the excess of air in the bowel.

**MARKETING AUTHORISATION HOLDER:**

sanofi-aventis S.p.A. - Viale Luigi Bodio, 37/B - 20158 Milan - Italy

**MANUFACTURER:**

sanofi-aventis S.p.A. - Viale Europa, 11 - 21040 Origgio (VA) - Italy

**WHY IT IS USED:**

MAALOX<sup>®</sup> PLUS is used as an adjuvant in gastric hyperacidity and dyspepsia (a reduced digestive activity) caused by hyperacidity also in the presence of meteorism (an exceeding presence of air in the bowel).

Symptomatic treatment of heartburn, stomach pain and esophagitis (inflammations of the first section of the digestive tract).

As an adjuvant in therapy of gastroduodenal ulcer.

**WHEN NOT TO USE MAALOX<sup>®</sup> PLUS:**

State of cachexia (a state of general body weakening).

Hypersensitivity to the product components or to other substances which are closely correlated from the chemical point of view.

Contraindicated in patients suffering from porphyria.

Severe kidney failure.

Generally contraindicated in children.

**When it may be used only after having consulted the doctor:**

In children, in case of pregnancy and lactation (see "What to do during pregnancy and lactation") and in the presence of a severe renal failure (see "Precautions for use").

It is appropriate to consult your doctor also if these disorders appeared in the past.

**WHAT TO DO DURING PREGNANCY AND LACTATION:**

Use the product only in cases of a true need and under the direct medical monitoring. During pregnancy and lactation, MAALOX<sup>®</sup> PLUS should be used only after having consulted your doctor and assessed with him/her the risk/benefit ratio in your individual case.

Consult your doctor if you suspect to be pregnant or if you plan to have a child.

**PRECAUTIONS FOR USE**

Chewable tablets contain saccharose: this should be taken into account in diabetic patients or in patients under low-calorie dietetic regimens.

As the product contains saccharose and glucose, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should avoid taking MAALOX<sup>®</sup> PLUS chewable tablets.

As the product contains sorbitol, patients with rare hereditary problems of fructose intolerance should avoid taking MAALOX<sup>®</sup> PLUS.

In the presence of a severe renal insufficiency, it is advisable to take the product under the control of a physician.

**WHICH DRUGS OR FOODS COULD CHANGE THE EFFECT OF THE DRUG:**

Since the Al and Mg salts reduce the gastroenteric absorption of tetracyclines, we recommend to exclude the intake of MAALOX<sup>®</sup> PLUS during therapies with tetracyclines by oral route.

The use of antacids containing aluminium may reduce the absorption of H<sub>2</sub> antagonists, atenolol, chloroquine, tetracyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazide, kayexalate, ketoconazole, lincosamides, methoprolol, phenothiazinic neuroleptics, penicillamines, propranolol, iron salts.

Wait at least 2 hours (4 for fluoroquinolones), before taking MAALOX<sup>®</sup> PLUS to avoid interaction with the other drugs.

Concomitant use of quinidine may determine an increase in serum quinidine levels and lead to a quinidine overdose.

The simultaneous use of aluminium hydroxide and citrates may lead to an increase in aluminium levels, particularly in patients with kidney failure.

If you are using other medicinal products, consult your physician or pharmacist.

**IT IS IMPORTANT TO KNOW THAT**

MAALOX<sup>®</sup> PLUS, due to its composition, has no tendency to modify the pattern of the bowel. However, in some particularly susceptible subjects and at high doses, an acceleration of the intestinal transit could occur. Do not use the drug for long-term treatments.

The drug may have an astringent effect and cause constipation. At high doses it may cause intestinal obstruction. After a short period of treatment without appreciable results, consult your doctor.

**HOW TO USE THIS DRUG:**

*Suspension:* 2-4 teaspoonfuls or 1-2 sachets 4 times daily, 20-60 minutes after meals and before bed resting. The product may be diluted in water or milk.

Shake thoroughly before use.

*Chewable tablets:* 2-4 chewable tablets 4 times daily, well chewed or sucked, 20-60 minutes after meals and before bed resting. Their intake could be followed by the ingestion of water or milk.

Attention: Never go over the doses mentioned without consulting a physician.

Consult your physician if the disorder appears repeatedly or if you have noticed any recent change in its features.

Attention: use the drug only for short period.

**OVERDOSE:**

There is very little experience of deliberate overdoses. An overdose with aluminium salts is more likely to occur in patients suffering from chronic severe kidney failure with the following symptoms: encephalopathy, convulsions and dementia.

As in all cases of overdose, treatment should be symptomatic and general supportive measures should be taken.

**ADVERSE EFFECTS:**

Undesired effects are not common at the recommended doses. Occasionally, however, following excessive use, diarrhoea or constipation may occur.

The compliance with the instructions contained in the package insert reduces the risk of adverse effects. It is important to inform the doctor or the pharmacist of any onset of adverse effects.

**EXPIRY AND STORAGE:**

*Suspension:* do not store above 25°C. Store above 4°C. Keep the bottle well stoppered.

*Chewable tablets:* store below 30°C.

Attention: never use the drug after the expiry date printed on the outer label.

Keep out of the reach and sight of children.

It is important to have always at disposal the information about the drug. Therefore, always keep the box and the package insert.

**Over-the-counter medicine.**

**Read carefully the package insert before use.**

**DATE OF LEAFLET REVISION:** April 2008