

1. NAME OF THE MEDICINAL PRODUCT

Maalox Plus Chewable Tablets 200mg/200mg/25mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

200 mg of Magnesium Hydroxide (as magnesium hydroxide paste)

200mg of Hydrated Aluminium Oxide

25mg of Dimeticone (as simeticone)

Excipients with known effect:	Sorbitol (E420) 45 mg
	Glucose 500.5 mg
	Sucrose 75 mg
	Ethanol 0.00004 mg
	Sulphur dioxide (E220) 13 ppm

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable Tablet.

Bi-layered, white/yellow tablets engraved with “Maalox” on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In the treatment of heartburn, indigestion, flatulence and dyspepsia.

4.2 Posology and method of administration

The route of administration is oral.

Recommended Dosage

Adults: One to two tablets four times a day (after meals and at bedtime) or as required.

Children: Not recommended

4.3 Contra-indications

Use in severely debilitated patients or in those suffering from kidney failure.

Use in patients who are hypersensitive to the active ingredients or to any of the excipients.

4.4 Special warnings and precautions for use

Aluminium hydroxide may cause constipation and magnesium salts overdose may cause hypomotility of the bowel; large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at higher risk such as those with renal impairment, infants less than 2 years, or the elderly.

Aluminium hydroxide is not well absorbed from the gastrointestinal tract, and systemic effects are therefore rare in patients with normal renal function. However, excessive doses or long-term use, or even normal doses in patients with low-phosphorus diets or in infants less than 2 years, may lead to phosphate depletion (due to aluminium-phosphate binding) accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Medical advice is recommended in case of long-term use or in patients at risk of phosphate depletion.

Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with extreme caution in patients with kidney disease.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, a long-term exposure to high doses of aluminium and magnesium salts may lead to encephalopathy, dementia, microcytic anemia or worsen dialysis-induced osteomalacia.

The prolonged use of antacids in patients with renal failure should be avoided.

Care should be observed if used by diabetics because of the sugar content in the tablet.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis because it has been shown that aluminium may be involved in porphyrin metabolism abnormalities.

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase –isomaltase insufficiency should not take this medicine.

Sulphur dioxide may rarely cause hypersensitivity reactions and bronchospasm.

Maalox Plus contains small amounts of ethanol (alcohol), less than 100mg per dose.

Prolonged use with antacids may mask symptoms of more serious diseases, such as gastrointestinal ulceration or cancer.

4.5 Interactions with other medicinal products and other forms of interaction

Aluminium hydroxide may form complexes with certain drugs, e.g. tetracyclines, digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

Concomitant use with quinidines may increase the serum levels of quinidine and lead to quinidine overdose.

Aluminium-containing antacids may prevent the proper absorption of H₂ antagonists, atenolol, cefdinir, cefpodoxime, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indometacin, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics, phenothiazines, penicillamine, propranolol, iron salts.

Staggering the administration times of the interacting drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones) will often help avoid undesirable drug interactions.

Polystyrene sulfonate (Kayexalate)

Caution is advised when used concomitantly with polystyrene sulfonate (Kayexalate) due to the potential risks of reduced effectiveness of the resin in binding potassium, of metabolic alkalosis in patients with renal failure (reported with aluminium hydroxide and magnesium hydroxide), and of intestinal obstruction (reported with aluminium hydroxide).

Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

4.6 Pregnancy and lactation

The use of Maalox Plus should be avoided during the first trimester of pregnancy.

Because of the limited maternal absorption when used as recommended, aluminium hydroxide and magnesium salts combinations are considered as compatible with lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable Effects

Side effects are uncommon at recommended doses

Immune system disorders

Not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions.

Gastrointestinal disorders

Uncommon: diarrhoea or constipation (see Section 4.4 Special warnings and precautions for use).

Metabolism and nutrition disorders

Very rare: hypermagnesemia including observations after prolonged administration of magnesium hydroxide to patients with renal impairment.

Not known:

- hyperaluminemia,

- hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets or in infants less than 2 years, which may result in increased bone resorption, hypercalciuria, osteomalacia (see Section 4.4 Special warnings and precautions for use).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

SIGNS AND SYMPTOMS

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting. Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see Section 4.4 Special warnings and precautions for Use)

MANAGEMENT

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of rehydration, forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary. Serious symptoms are unlikely following overdosage.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Maalox Plus is a balanced mixture of two antacids and simethicone: aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a fast-acting one. The two are frequently combined in antacids mixtures. Aluminium hydroxide on its own is astringent and may cause constipation. This effect is balanced by the effect of magnesium hydroxide, which, in common with other magnesium salts, may cause diarrhoea. Simethicone is a surface-active agent included to disperse form. This reduces gastroesophageal reflux. It does not have antacid properties.

5.2 Pharmacokinetic properties

The absorption of aluminium and magnesium from antacids is small. Aluminium hydroxide is slowly converted to aluminium chloride in the stomach. Some absorption of soluble aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

5.3 Preclinical safety data

Not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose
Mannitol
Sorbitol liquid non-crystallising
Sorbitol
Saccharin sodium
Magnesium stearate
Talc
Pregelatinised maize starch
Maize starch
Citric acid, anhydrous
Glucose, anhydrous
Lemon flavour (contains sulphur dioxide)
Swiss cream flavour (contains sulphur dioxide and ethanol)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and Contents of container

PVC/aluminium blister packs in outer carton: 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 80, 84, 90, 96 and 100 tablets.

Not all pack sizes are marketed.

6.6 Instructions for Use/Handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

sanofi-aventis Ireland Ltd T/A SANOFI.
Citywest Business Campus
Dublin 24

8. MARKETING AUTHORISATION NUMBER

PA 540/109/2

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10th November 1985/ 1st October 2009.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

November 2017