1. NAME OF THE MEDICINAL PRODUCT

Maalox Plus Suspension

Maalox Plus Chewable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Maalox Plus Suspension**

5ml of the suspension contains: 225mg of Aluminum Hydroxide (as aluminium hydroxide gel), 25mg of simethicone and 200mg of Magnesium Hydroxide (as magnesium hydroxide paste).

**Maalox Plus Chewable Tablets**

Each tablet contains 200 mg of Magnesium Hydroxide (as magnesium hydroxide paste), 200mg of Hydrated Aluminium Oxide and 25mg of Simeticone.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

White suspension with the odour and taste of lemon. A white lemon flavoured oral suspension.

Chewable Tablet

Bi-layered, white/pale yellow circular, bevel-edged, lemon flavoured chewable tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Antacid, antiflatulent, relief of sensation of heatburn

4.2 Posology and method of administration

For oral administration The route of administration is oral.

Recommended Dosage:

**Maalox Plus Suspension**

**Adults**

5-10ml, four times a day, taken 20 minutes to 1 hour after meals and at bedtime or as required.
Children

Child 6–12 years 5 mL 3–4 times daily
Child 12–18 years 5–10 mL 4 times daily, taken 20 minutes to 1 hour after meals and at bedtime when required

Elderly
The normal adult dose is appropriate.

Maalox Plus Chewable Tabs

Adults (including elderly persons): 1-2 tablets well chewed, four times a day, taken twenty minutes to one hour after meals and at bedtime, or as required.

Children: Not recommended.

4.3 Contraindications

Known Hypersensitivity to any of the active substances or excipients.

Maalox Plus should not be used in patients who are severely debilitated or suffering from renal insufficiency, or hypophosphataemia or if there is severe abdominal pain and/or the possibility of bowel obstruction.

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

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, or the elderly.

Aluminium hydroxide may cause constipation due to its astringent action, this effect may be balanced by the carthartic effect of the magnesium salts.
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 osteomalacia.
The prolonged use of antacids in patients with renal failure should be avoided.

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

**Maalox plus Tablets**

This product contains sorbitol [E420]. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

**Maalox plus suspension:**

This product contains sorbitol [E420]. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains methyl paraben [E218] and propyl paraben [E216]; these may cause allergic reactions (possibly delayed).

4.5 Interactions with other medicinal products and other forms of interaction

Maalox Plus should not be taken simultaneously with other medicines as they may interfere with their absorption if taken within 1 hour.

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.

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

Aluminium-containing antacids may prevent the proper absorption of drugs such as ciprofloxacin, H2 antagonists, atenolol, cefdinir, cefpodoxime, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluorour, glucocorticoids, indometacine, isoniazide, ketoconazole, levothyroxine, lincosamides, metoprolol, neuroleptics phenothiazines, pencilamine, propranolol, rosuvastatin, iron salts.

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

**Levothyroxine may also bind to simeticone which may delay or reduce the absorption of levothyroxine.**

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).

Aluminum hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.
4.6 **Fertility, Pregnancy and lactation**

The safety of Maalox Plus in pregnancy has not been established.

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. Minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

Simeticone is not absorbed from the gastrointestinal tract.

No effect on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simeticone is negligible.

4.7 **Effects on ability to drive and use machines**

None stated.

4.8 **Undesirable Effects**

The following CIOMS frequency rating is used, when applicable:

- Very common (≥ 1/10), common (≥ 1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).

The following CIOMS frequency rating is used, when applicable:

- Very common ≥ 10 %; Common 1 and <10 %; Uncommon 0.1 and < 1 %;
- Rare 0.01 and < 0.1 %; Very rare < 0.01 %; Unknown (cannot be estimated from available data).

Side effects are uncommon at recommended doses.

**Immune system disorders**

Frequency not unknown: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

**Gastrointestinal disorders**

Gastrointestinal side-effects are uncommon.

Uncommon: diarrhea or constipation (see Section 4.4).

**Metabolism and nutrition disorders**

Frequency not unknown:
- hypermagnesemia,
- 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).
4.9 Overdosage

Signs and symptoms

Serious symptoms are unlikely following overdosage.

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

Management

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulents, ATC Code: A02AF02

Dried aluminium hydroxide gel - antacid
Magnesium Hydroxide - antacid
Simeticone - antifoaming agent/antiflatulent

Maalox is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simethicone.

The two antacids are aluminum hydroxide which is a slow acting antacid and magnesium hydroxide which is a fast acting one. The combination produces a fast onset of action and an increase in total buffering time. The two are frequently combined in antacid 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 aluminum and magnesium from antacids is small. Aluminum hydroxide is slowly converted to aluminum chloride in the stomach. Some absorption of soluble aluminum salts occurs in the gastrointestinal tract with urinary excretion. Any absorbed magnesium is likewise excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.
6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

**Maalox Plus susp**
Sorbitol liquid as dried sorbitol- 224.85 mg/ml, Hydroxypropylcellulose, Methylparaben, Microcrystalline cellulose + Carmellose Sodium, Natural lemon concentrate, Citric Acid anhydrous, Swiss Crème flavor, Propylparaben, Methylcellulose, Sodium Saccharine- 1.125 mg/5ml, Hydrogen peroxide 35%, Purified water.

**Maalox Plus Chewable Tabs**
Glucose anhydrous- 500.50 mg/tab, Maize starch, Mannitol- 75 mg/tab, Sucrose- 75mg/tab, Sorbitol liquid non-crystallizing- 32.80mg/ml (corresponding to 22.96 mg of Sorbitol), Sorbitol - 22.04 mg/tab, Talc, Magnesium Stearate, Pregelatinized starch (Maize starch), Lemon Flavor, Citric Acid anhydrous, Saccharine sodium, Swiss Cream flavor, Iron oxide yellow (E-172).

6.2 Incompatibilities
Not applicable

6.3 Special precautions for storage

**Maalox Plus suspension**
Do not store above 25°C. Do not freeze. Shake well before using. Keep bottle tightly closed. Once opened use within 28 days of opening.

**Maalox Plus Chewable tabs**
Do not store above 25°C. Do not freeze. Store in the original package in order to protect from moisture.

7. MANUFACTURER Sanofi-aventis S.P.A., Italy

8. MARKETING AUTHORISATION HOLDER sanofi-aventis Israel Ltd.