1. NAME OF THE MEDICINAL PRODUCT

Maalox Plus 200mg/175mg/25mg Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of the suspension contains:

200mg of Magnesium Hydroxide (as Magnesium Hydroxide Paste).
175mg of Aluminium Hydroxide (as Aluminium Hydroxide Gel)
25mg of Simeticone

Excipients: Each 5ml also contains 224.85mg sorbitol (E420), 1.66mg sodium, 3.667mg ethanol, 3ppm sulphur dioxide (E220).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.

A white lemon flavoured oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

The route of administration is oral.

Recommended Dosage

Adults: One to Two x 5ml spoonfuls 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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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.

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.

Pronlonged 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., digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

Because of the aluminium content, Maalox Plus should not be concomitantly administered with tetracycline containing antibiotics or any tetracycline salts.

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 overdosage.

Aluminium-containing antacids may prevent the proper absorption of H2 antagonists, atenolol**,** cefdinir, cefpodoxime, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluorure, glucocorticoids, indometacine, isoniazide, kayexalate, ketoconalzole, lincosamides, metoprolol, neuroleptics phenothiazines, pencillamine, propranolol, 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.

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 Fertility, pregnancy and lactation

There are no available data on Maalox use in pregnant women. No conclusions can be drawn regarding whether or not Maalox is safe for use during pregnancy. Maalox should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the foetus.

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 precaution s 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 precaution s 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 HPRA 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 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 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 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

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Domiphen bromide
Methylcellulose
Microcrystalline cellulose
Carmellose Sodium
Hyprolose
Citric Acid, monohydrate
Saccharin sodium
Sorbitol 70% liquid non crystallising (E420)
Hydrogen Peroxide 30%
Natural Lemon concentrate (contains ethanol)
Swiss Crème Flavour (contains ethanol and sulphur dioxide (E220))
Purified Water.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30°C. Do not freeze. Keep the bottle tightly closed.
The product should be used within 6 months of first opening the bottle.

6.5 Nature and Contents of container

White PET bottles with plastic screw cap: 250ml and 355ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PA 540/109/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

10 November 1985/ 01 October 2009.

10. DATE OF (PARTIAL) REVISION OF THE TEXT

October 2019.