Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Maalox Sachets 460mg/400mg Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 460mg Aluminium hydroxide (aluminium oxide hydrated) and 400mg Magnesium hydroxide.

Excipients: Each 4.3ml sachet also contains 140mg of sorbitol (E420) and 3144.32 mg of Sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension

White to faintly yellow homogeneous suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of the symptoms of dyspepsia.

4.2 Posology and method of administration

The route of administration is oral.

Recommended Dosage

Adults: One to Two sachets taken 20 minutes to one hour after meals and at night as required or as directed by the physician

4.3 Contraindications

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 caution in patients with advance renal 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.

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.

Due to the presence of sorbitol and sucrose in this product, patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption ro sucrose-isomaltase insufficiency should not take this medicine.

May be harmful to teeth.

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

4.5 Interaction 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.

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, ketoconazole, levothyroxine, lincosamides, metoprolol, nueroleptic phenothiazines, penicillamine, propranolol, rosuvastatin, 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 Fertility, pregnancy and lactation

The product should not be used during pregnancy unless considered essential by the physician.

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
Frequency unknown: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions 1

Gastrointestinal disorders
Uncommon: diarrhoea or constipation (see Section 4.4 Special warnings and precaution s for Use)

Metabolism and nutrition disorders
Frequency 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 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

ATC: A02AD01

Maalox is a balanced mixture of two antacids: 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.

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 solution 64%
Sorbitol liquid (non-crystallising)
Xanthan gum
Guar
Sodium Chloride
Hydrogen peroxide solution 30%
Natural lemon lime flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

As packaged for sale: 36 months.
After first opening the sachet: Use immediately.

6.4 Special precautions for storage

No special storage requirements.

6.5 Nature and contents of container

Polypropylene-Aluminium-Polyethylene sachets each containing 4.3ml of oral suspension.
20 sachets per carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Limited T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0540/110/006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th July 2015

10 DATE OF REVISION OF THE TEXT

September 2016