Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Maalox 400mg/400mg Chewable Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
400 mg of Aluminium oxide, hydrated
400 mg of Magnesium Hydroxide.

Excipients: Each tablet contains 192mg confectioners sugar (containing no less than 97% sucrose), 125mg sorbitol (E420) and 59.2 mg sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Chewable Tablet
Flat, circular, bevel-edged white chewable tablet of diameter 1.4 cm with 'Mx' engraved on both sides and having an odour of peppermint.

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: 1-2 tablets chewed 4 times daily, taken 20 minutes to 1 hour after meals and at bedtime, or as directed by the physician. A maximum of 8 tablets in a 24 hour period should not be exceeded, nor should the maximum dose continue for more than 2 weeks except under the direction of the physician.

Children: Not recommended

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 antacid in patients with renal failure should be avoided.

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

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 interactions

This product 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 quindines may increase the serum levels of quinidine and lead to quinidine overdosage.

Aluminium-containing antacids may prevent the proper adsorption of other drugs notably H2 antagonists, atenolol, bisphosphonates, cefdinir, cefpodoxime, chloroquine, cyclines, dasatinib monohydrate, difunisal, digoxin, dexamethasone, eltrombopag olamine, elvitegravir, ethambutol, fluroquinolones, glucocorticoids, indomethacin, iron salts, isoniazid, , ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, phenothiazine neuroleptics, penicillamine, propranolol, raltegravir potassium, rilpivirine, riociguat, rosuvastatin, sodium fluorure and antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium.

With the integrase inhibitors (dolutegravir, raltegravir, bictegravir) the combination should be avoided (please refer to their SmPC for dose recommendations).

As a precaution, staggering the administration times of any orally administered drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

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 precautions for use).
Not known: abdominal pain.

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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

SIGNS AND SYMPTOMS
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 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: 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

Mannitol (E421)
Confectioners sugar (Contains Sucrose and maize starch)
Saccharin sodium
Sorbitol (E420)
Sucrose
Peppermint flavour powder
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

Tablets are packed in PVC/aluminium blister strips 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 80, 84, 90, 96 and 100 tablets in a cardboard outer.

Not all pack sizes are 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

Opella Healthcare France SAS T/A Sanofi
82 Avenue Raspail
94250 Gentilly
France

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 1982

Date of last renewal: 01 October 2009

10 DATE OF REVISION OF THE TEXT

October 2021