1. NAME OF THE MEDICINAL PRODUCT

Maalox Plus Chewable Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 200 mg of magnesium hydroxide, 200 mg of aluminium oxide hydrated and 25 mg of dimethicone (corresponding to simethicone (considering 5% of silica) – the active form) 26.52 mg.

Excipients with known effect:
500.50 mg of glucose anhydrous, 75 mg of sucrose, 32.80 mg of sorbitol liquid non-crystallising, 22.04 mg of sorbitol.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Antacid, antiflatulent, relief of sensation of heartburn

4.2. Posology and method of administration

For oral administration.

Recommended Dosage:

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

Should not be used in patients who are hypersensitive to the active ingredients or to any of the excipients, are severely debilitated or suffering from kidney failure.

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 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 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.

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 anaemia, or worsen dialysis-induced osteomalacia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

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

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium free”.

4.5. Interaction 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-containing antacids may prevent the proper absorption of drugs such notably H_2 antagonists, atenolol, bisphosphonates, cefdinir, cefpodoxime, chloroquine, chlorpromazine, ciprofloxacin, cyclines, dasatinib monohydrate, dexamethasone, diflunisal, digoxin, eltrombopag olamine, elvitegravir, ethambutol, fluoroquinolones, glucocorticoids, hydroxychloroquine, indomethacin, iron salts, isoniazid, ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, penicillamine, phenothiazine neuroleptics, propranolol, raltegravir potassium, rifampicin, rilpivirine, riociguat, rosuvastatin, sodium fluoride, antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, tetracyclines, and vitamins.

With the integrase inhibitors (dolutegravir, raltegravir, bictegravir) the combination should be avoided (please refer to their SmPC for dose recommendations).
As a precaution, stagger the administration times of any orally administered drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

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

Polystyrene sulphonate:
Caution is advised when used concomitantly with polystyrene sulphonate due to the potential risk 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).

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

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

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

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

4.6. Fertility, Pregnancy and lactation

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

Pregnancy:
There are no available data on Maalox Plus use in pregnant women. No conclusions can be drawn regarding whether or not Maalox Plus is safe for use during pregnancy. Maalox Plus should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the foetus.
Lactation:
Because of the limited maternal absorption when used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk.

Simethicone is not absorbed from the gastrointestinal tract.

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simethicone 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).

<u>Immune system disorders</u>
Frequency not known: Hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

<u>Gastrointestinal disorders</u>
Gastrointestinal side-effects are uncommon.
Uncommon: Diarrhoea or constipation (see section 4.4).
Frequency not known: Abdominal pain
Injury, poisoning and procedural complications:

Frequency not known:
Hyperaluminaemia (related to aluminium component).

Metabolism and nutrition disorders
Very rare: Hypermagnesaemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment

Frequency not known:
Hyperaluminaemia
Hypophosphataemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets which may result in increased bone resorption, hypercalciuria, osteomalacia (see section 4.4).

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il/

4.9. Overdose

Serious symptoms are unlikely following overdosage.

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).

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of 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

Aluminium oxide hydrated	- antacid
Magnesium hydroxide	- antacid
Simethicone	- antifoaming agent/antiflatulent

The antacids are balanced such that gastrointestinal side effects (constipation and diarrhoea) are minimal.

5.2. Pharmacokinetic properties

None stated

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Glucose anhydrous, maize starch, mannitol, sucrose, sorbitol liquid non-crystallizing, sorbitol, talc, magnesium stearate, pregelatinized starch (maize starch), lemon flavour, citric acid anhydrous, saccharin sodium, Swiss cream flavour, iron oxide yellow (E-172).

6.2. Incompatibilities

None stated.

6.3. Shelf life

The expiry date is indicated on the packaging materials.

6.4. Special precautions for storage

Store below 25°C.
Store in the original package in order to protect from moisture.

6.5. Nature and contents of container

PVC /aluminium strip packs.
Packs of 40 or 50 tablets. Not all pack sizes may be available.

7. MANUFACTURER

Opella Healthcare International SAS, 82 avenue Raspail, 94250 Gentilly, France

8. MARKETING AUTHORISATION HOLDER AND IMPORTER

Pharmashalom LTD, 21 Ha'Melacha Street, Afek Industrial Zone 4809157 ROSH-HA'AYIN, Israel.

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