1. NAME OF THE MEDICINAL PRODUCT

Maalox Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of the suspension contains:
200 mg of magnesium hydroxide and
175 mg of aluminium hydroxide.

Excipients with known effect:
This medicinal product contains 0.0068 mmol (0.157 mg) of sodium and 50 mg of sorbitol per 5 ml dose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension.
White suspension, homogenous after shaking.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Antacid

4.2. Posology and Method of Administration

Posology

Recommended Dosage

Adults (including the elderly):
10-20 ml taken 20 minutes to one hour after meals and at bedtime or as required.
Maalox can be taken with water or milk if required.

Children:
Not recommended for children under 14 years.

Method of administration
For oral administration. Shake before use

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

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

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 dementia, microcytic anaemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis.

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

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

Aluminium-containing antacids are known to interfere with the absorption of drugs notably H_2 antagonists, atenolol, bisphosphonates, chloroquine, chlorpromazine, cefdinir, cefpodoxime, ciprofloxacin, cyclines, dasatinib monohydrate, diflunisal, digoxin, dexamethasone, eltrombopag olamine, elvitegravir, ethambutol, fluoroquinolones, glucocorticoids, hydroxychloroquine, indomethacin, iron salts, isoniazid, ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, phenothiazine neuroleptics, penicillamine, 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).

<u>Polystyrene sulphonate</u>
Caution is advised when used concomitantly with polystyrene sulphonate 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.

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

Pregnancy
There are no or limited amount of data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Maalox is not recommended during the first trimester of pregnancy and in women of childbearing potential not using contraception. Caution should be exercised when prescribing to pregnant and lactating women.

Breast-feeding
Because of the limited maternal absorption, when used as recommended, aluminium hydroxide and magnesium salt combinations are considered compatible with lactation.

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

Fertility
No fertility data is available.

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)

Immune system disorders
Not known: Hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders
Gastrointestinal side effects are uncommon.
Uncommon: Diarrhoea or constipation (see section 4.4).
Frequency not known: Abdominal pain

Metabolism and nutrition disorders
Very rare: Hypermagnesemia, 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 overdose. Discontinue medication and correct fluid deficiency if necessary.

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

Pharmacotherapeutic group: Antacids; aluminium compound combinations
ATC code: A02AB10

Maalox is a balanced mixture of two antacids; aluminium hydroxide is a slow-acting antacid and magnesium hydroxide is a quick-acting one. The two are frequently combined in antacid mixtures. Aluminium hydroxide on its own is an 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. Gastro-intestinal side effects are thus rare with Maalox and this makes it especially suitable when long term therapy is necessary.

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. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur.

5.3. Preclinical Safety Data

Non-clinical data are limited and are considered insufficient with respect to repeated dose toxicity, genotoxicity and toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Sorbitol liquid 70% (non-crystallizing)
Hydrochloric acid 10%
Mannitol
Citric acid monohydrate
Hydrogen peroxide solution 30%
Saccharin sodium
Peppermint oil
Domiphen bromide
Purified water

6.2. Incompatibilities

None stated.

6.3. Shelf life

The expiry date is indicated on the packaging materials.
Shelf life after first opening: 6 months.

6.4. Special Precautions for Storage

Store below 25^{o}C. Do not freeze. Keep bottle tightly closed.

6.5. Nature and contents of container

White polyethylene terephthalate (PET) bottles with polypropylene (PP) closure and polyethylene (PE/LDPE) liner containing 250 ml and 355 ml and a measuring cup.

Not all pack sizes may be marketed.

7. MANUFACTURER

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

8. MARKETING AUTHORISATION HOLDER

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

Revised in August 2024.