



Chewable Tablets - Suspension

**Aluminum Hydroxide (dried gel) + Magnesium Hydroxide + Simethicone
200/200/25 mg - 220/195/25 mg.**

Composition:

- Chewable tablet: Each Chewable tablet contains: Aluminum Hydroxide gel (dried) 200 mg, Magnesium hydroxide 200mg, Simethicone 25mg.
- Suspension: Each 5 mL contains:Dried Aluminum Hydroxide gel 220 mg, Magnesium Hydroxide 195 mg, Simethicone 25 mg.

Excipients:

- Chewable tablet: Dextrose, Dipac Sugar, Microcrystalline Cellulose, Peppermint Flavor, Stearic Acid.
- Suspension: Methyl paraben (E218), Propyl paraben (E216), Methylcellulose, Microcrystalline cellulose & Na CMC, Hydroxy Propyl Cellulose Citric Acid monohydrate, Saccharin sodium, Sorbitol solution 70%, Natural Lemon concentrate ,Swiss crème flavor.

Pharmacodynamics:

Maalox Plus 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 antacids 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. This reduces gastroesophageal reflux. It does not have antacid properties.

Pharmacokinetics:

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.

Uses:

- for the relief of:
- acid indigestion,
- heartburn,
- sour stomach,
- upset stomach associated with these symptoms,
- pressure and bloating commonly referred to as gas.

INDICATIONS:

As an antacid for symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, or hiatal hernia. As an antiflatulent to alleviate the symptoms of gas, including postoperative gas pain.

DIRECTIONS:

- Chewable tablets:
- chew 1-2 tablets between meals and at bedtime,
- do not take more than 24 tablets in a 24 hour period,
- do not use the maximum dose for more than 2 weeks.

- Suspension:

Shake well before using.
Adults and children 12 years and older: 10 mL to 20 mL (2 to 4 teaspoonfuls) four times a day or as directed by a physician.
Children under 12 years: consult a physician.
do not take more than 40 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks,
except under the advice and supervision of a physician.

WARNINGS:

The maximum recommended daily dosage of this product is 80 mL (16 teaspoonfuls). Do not take more than this dosage in a 24-hour period or use this dosage for more than 2 weeks except under the advice and supervision of a physician. Do not use this product except under the advice and supervision of a physician if you have kidney disease. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Prolonged use of aluminium-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. Elevated discal aluminium levels contribute to the development of the dialysis encephalopathy and osteomalacia syndromes. Small amounts of aluminium are absorbed from the gastrointestinal tract and renal excretion of aluminium is impaired in renal failure. Aluminium is not well removed by dialysis because it is bound to albumin and transferrin, which do not cross dialysis membranes. As a result, aluminium is deposited in bone, and dialysis osteomalacia may develop when large amounts of aluminium are ingested orally by patients with impaired renal function.

Aluminium forms insoluble complexes with phosphate in the gastrointestinal tract, thus decreasing phosphate absorption. Prolonged use of aluminium-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

Drugs interactions:



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.

Urinary 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 overdose.

Aluminium-containing antacids may prevent the proper absorption of H2 antagonists, atenolol, cefdinir, cefpodoxime, chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucorticoids, indometacine, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics, phenothiazines, penicillamine,

propranolol, iron salts.

Slaggering 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.

Causticene sulfonate (Kayexalate):

Causticene 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.

Pregnancy and lactation:

The use of this product should be avoided during the first trimester of pregnancy.

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

Side effects:

Uncommon: diarrhea or constipation .

Not known: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions, hyperaluminuria,

- 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, hypercalcemia, osteomalacia .

Overdosage:

-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

-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.

Storage conditions:

- Chewable tablet: Store out of reach of children, between 15-30°C.

- Suspension: Methyl paraben (E218), Propyl paraben (E216), Methylcellulose, Microcrystalline cellulose & Na CMC, Hydroxy Propyl Cellulose Citric Acid monohydrate, Saccharin sodium, Sorbitol solution 70%, Natural Lemon concentrate, Swiss crème flavor.

Packaging:

- Chewable tablet: A carton box contains 2 opaque pvc/alu blister strips, each contains 10 tab.

- Suspension: A bottle of (100 ml) or (200 ml) in a carton box.

THIS IS A MEDICAMENT 04/2022

-A medicament is a product but unlike any other products.
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-Follow strictly the physician's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The physician and the pharmacist are experts in medicine, its benefits and risks.
-Do not by yourself interrupt the period of treatment prescribed for you.
-Do not repeat the same prescription without consulting your physician.

KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN

(Council of Arab Health Ministers) (Arab Pharmacists Association)



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