

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. Name of the medicinal product

Stopacid Suspension

2. Qualitative and quantitative composition

Each 5ml contains:

Magnesium Hydroxide	200mg
Aluminium Hydroxide	225mg
Simethicone	50mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Suspension.

A creamy white suspension.

4. Clinical particulars

4.1 Therapeutic indications

Stopacid® is indicated in symptomatic relief from hyper-acidity associated with;

- 🌐 Peptic ulcer
- 🌐 Reflux oesophagitis
- 🌐 Gastritis
- 🌐 Heartburn
- 🌐 Flatulence

4.2 Posology and method of administration

Adults and children over 12 years: 5 - 10 ml about one hour after

meal 3- 4
times daily.

Children 5- 12 years: 5ml after meal 3-4 times daily

Method of Administration

Oral administration only

4.3 Contraindications

Stopacid suspension should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia.

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-phosphorous 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 anemia or worsen dialysis-induced osteomalacia.

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

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

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

4.5 Interaction with other medicinal products and other forms of interaction

Stopacid 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 as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H₂ antagonists, atenolol, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine, propranolol and iron salts.

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

Polystyrene sulphonate

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).

Quinidine:

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

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 Pregnancy and Lactation

The safety of Stopacid Suspension in pregnancy has not been established.

Pregnancy:

There are no available data on Stopacid use in pregnant women. No conclusions can be drawn regarding whether or not Stopacid is safe for use during pregnancy. Stopacid should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

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.

Simeticone is not absorbed from the gastrointestinal tract. No effect on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simeticone is negligible.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Excessive doses, or even normal doses of Aluminium hydroxide in patients with low-phosphate diets, may lead to phosphate depletion, accompanied by increased bone resorption and hypercalciuria with the risk of osteomalacia. Encephalopathy, dementia and microcytic anaemia have been associated with aluminium accumulation in patients with chronic renal failure.

Hypermagnesaemia have also been reported in patients with impaired renal function.

symptoms of hypermagnesaemia include CNS and respiratory depression, hyporeflexia, vasodilation, hypertension, cardiac arrhythmias and cardiac arrest.

4.9 Overdose

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.

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: Drugs for acid related disorders; Antacids with antiflatulents, ATC Code: A02AF02

Dried aluminium hydroxide - antacid

- antacid

Magnesium Hydroxide

- antifoaming agent/antiflatulent

Simeticone

Stopacid is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simeticone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium citrate
Menthol
crystal Methyl
paraben
Propyl paraben
Xanthan gum
Bronopol
Citric acid
Alcohol

Glycerine
Sodium saccharine
Sorbitol Solution
Peppermint oil
Tutti frutti flavour

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30 ° C.

6.5 Nature and contents of container

Stopacid suspension is packaged in Amber glass bottle of 200ml

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. APPLICANT/MANUFACTURER

Afrab Chem Limited
22 Abimbola Street, Isolo Ind. Estate, Isolo-Lagos