

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Aluminium hydroxide/magnesium hydroxide/simethicone 400 mg/318.4 mg/50 mg per 10 mL oral gel
Soothe-gel

2. Qualitative and quantitative composition

Each 5 mL (approximately a teaspoon) contains 200 mg of aluminium hydroxide, 159.2 mg of magnesium hydroxide and 12.5 mg of simethicone.

Excipient with known effect

Each 5mL also contains 1g of sorbitol, 1 mg of propyl hydroxybenzoate and 10 mg of methyl hydroxybenzoate (section 4.4).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral gel.

Pink suspension with a characteristic mint flavour.

4. Clinical particulars

4.1 Therapeutic indications

The symptomatic relief of:

1. Dyspepsia.
2. Heartburn.
3. Flatulence.
4. Acid reflux.
5. Acid indigestion.

4.2 Posology and method of administration

The bottle should be shaken before use.

Adults

Two to six medicine measures (10 ml - 30 ml) every three hours daily as required. Do not exceed a total daily dose of 180 ml.

Adolescents

One to four medicine measures (5 ml - 20 ml) every three hours daily as required. Do not exceed a total daily dose of 120 ml.

Children under 12years

Maximum of one medicine (5 ml) measured three times a day.
The daily recommended dose is 5 mg (10 ml of solution).

4.3 Contraindications

Hypersensitivity to the active substance or any of the other excipients listed in section 6.1. Aluminium hydroxide/magnesium hydroxide/simethicone is also contraindicated in patients who are severely debilitated or suffering from kidney failure, or hypophosphataemia.

4.4 Special warnings and precautions for use

Precaution is recommended with concurrent intake of alcohol (see section 4.5).

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 patients at risk of phosphate depletion.

In patients with renal impairment, plasma levels of both aluminium and magnesium increase. In these patients, 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.

Paediatric population

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

Excipients

This medicine contains **sorbitol**. Sorbitol is a source of fructose. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. 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 medicine contains **methyl hydroxybenzoate** and **propyl parahydroxybenzoate** which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide/magnesium hydroxide/simethicone 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 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 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

Aluminium hydroxide/magnesium hydroxide/simethicone should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts because of the aluminium content.

Citrates

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

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

4.6 Pregnancy, lactation and fertility

Pregnancy

There is no available data on aluminium hydroxide/magnesium hydroxide/simethicone use in pregnant women. No conclusions can be drawn regarding whether or not aluminium hydroxide/magnesium hydroxide/simethicone is safe for use during pregnancy. Aluminium hydroxide/magnesium hydroxide/simethicone should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the foetus.

Breastfeeding

When used as recommended, minimal amounts, if any, of aluminium hydroxide and magnesium salt combinations are expected to be excreted into breast milk because of the limited maternal absorption.

Simethicone is not absorbed from the gastrointestinal tract.

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

4.7 Effects on the ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Very common ($\geq 1/10$), common ($\geq 1/100$ to $<1/10$), uncommon ($\geq 1/1,000$ to $<1/100$), rare ($\geq 1/10,000$ to $<1/1,000$), very rare ($<1/10,000$), not known (cannot be estimated from available data).

Immune system disorders

Frequency 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

Injury, poisoning and procedural complications

Frequency not known: Hyperaluminemia (related to Aluminum component).

Metabolism and nutrition disorders

Very rare: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairment

Frequency not known: Hyperaluminemia

Hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low-phosphorus diets may result in increased bone resorption hypercalciuria and 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. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications

(https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on Google Play or Apple App Store.

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, and 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 the 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

Pharmacological classification: 16.1 Antiacids.

Mechanism of action

Aluminium hydroxide/magnesium hydroxide/simethicone is a balanced mixture of two antacids and an antifatulent/antifoaming agent simethicone. The two antacids are magnesium hydroxide which is 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 and may cause diarrhoea.

5.2 Pharmacokinetic properties

None stated as Soothe-gel suspension activity is non-systemic.

5.3 Preclinical safety data

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

6. Pharmaceutical particulars

6.1 List of excipients

Sorbitol
Peppermint oil
Methyl hydroxybenzoate
Propyl hydroxybenzoate
Saccharin sodium
Raspberry red
Sodium hypochlorite
Triacetin
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C.

6.5 Nature and contents of the container

A round HDPE bottle with a white LDPE cap or a Type III glass bottle with a plastic screw cap.

Fill volume: 100 ml and 200 ml.

Pack size: 1 bottle per carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

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8. MANUFACTURER

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9. REGISTRATION DETAILS

Zimbabwe registration number: 2023/16.1/6472

Zimbabwe category for distribution: Household Remedies (H.R.)

10. DATE OF REVISION OF THE TEXT

November 2023