

1.3.1

Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1.3.1.1 Invented Name of the Medicinal Product

GRENOCID SUSPENSION

Alumina, Magnesia, and Simethicone Oral suspension USP

1.3.1.2 Strength

Each 5 ml Contains:

Aluminium Hydroxide Gel USP

(Eq. to Aluminium Hydroxide 191.25mg) 250 mg

Magnesium Hydroxide USP 250 mg

Simethicone USP50 mg

Excipients: Q.S.

Colour: Permitted Colour

Flavour Mint

1.3.1.3 Dosage Form

Oral Suspension

1.3.1.4 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml Contains:

Aluminium Hydroxide Gel USP

(Eq. to Aluminium Hydroxide 191.25mg) 250 mg

Magnesium Hydroxide USP 250 mg

Simethicone USP50 mg

Excipients: Q.S.

Colour: Permitted Colour

Flavour: Mint

1.3.1.5 PHARMACEUTICAL FORM

Oral Suspension

Pink coloured, mint flavored suspension.

1.3.1.6 CLINICAL PARTICULARS

1.3.1.6.1 Therapeutic indications

The symptomatic relief of:

1. Dyspepsia.
2. Heartburn.
3. Flatulence.

1.3.1.6.2 POSOLOGY AND METHOD OF ADMINISTRATION

For oral administration:

Adults

5-10ml taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5 ml t.d.s.

Elderly

The normal adult dose is appropriate.

1.3.1.6.3 CONTRAINDICATIONS

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.

1.3.1.6.4 WARNING AND PRECAUTIONS

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.

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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.

1.3.1.6.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER**FORMS OF INTERACTION**

GRENOCID SUSPENSION 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, GRENOCID SUSPENSION 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.

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

1.3.1.6.6 PREGNANCY AND LACTATION

The safety of GRENOCID SUSPENSION in pregnancy has not been established.

Pregnancy:

There are no available data on GRENOCID SUSPENSION use in pregnant women. No conclusions can be drawn regarding whether or not GRENOCID SUSPENSION is safe for use during pregnancy. GRENOCID SUSPENSION 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.

1.3.1.6.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None stated.

1.3.1.6.8 UNDESIRABLE EFFECTS

The following CIOMS frequency rating is used, when applicable:

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

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

Gastrointestinal disorders

Gastrointestinal side effects are uncommon.

Uncommon: diarrhoea or constipation.

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

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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, which may result in increased bone resorption, hypercalciuria, osteomalacia .

1.3.1.6.9 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.

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.

1.3.1.7 PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antifoaming agents, ATC Code: A02AF02

Dried aluminium hydroxide gel - antacid

Magnesium Hydroxide - antacid

Simeticone - antifoaming agent/antiflatulent

GRENOCID SUSPENSION 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.

Pharmacokinetic properties

None stated

1.3.1.8. PHARMACEUTICAL PARTICULARS

1.3.1.8.1 List of excipients

Generic Name: Alumina, Magnesia, and Simethicone Oral suspension USP (Administrative File)

Sr. No.	Name of Ingredients	Specification
01.	Sorbitol Solution 70%	BP
02.	Methyl Paraben Sodium	BP
03.	Propyl Paraben Sodium	BP
04.	Bronopol	BP
05.	Sodium Carboxy Methyl Cellulose	BP
06.	Guar Gum	BP
07.	Sodium Citrate	BP
08.	Sodium Saccharine	BP
09.	Colour Erythrosine Red	BP
10.	Chloroform	BP
11.	Flavor Raspberry	BP
12.	Peppermint Oil	IHS
13.	Menthol	IHS

1.3.1.8.2 Incompatibilities:

None stated.

1.3.1.8.3 Shelf life:

3 years

1.3.1.8.4 Special precautions for storage:

Store below 30°C and protected from moisture.

1.3.1.8.5 Nature and contents of container:

200 ml. Pink coloured, mint flavored suspension filled in amber colour glass bottle duly sealed with silver colour metallic cap having printed "GRENOCID" on the top

1.3.1.8.6 Special precautions for disposal and other Special handling:

No special requirements.

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

Brand Name: GRENOCID SUSPENSION

Module 1

Generic Name: Alumina, Magnesia, and Simethicone Oral suspension USP (Administrative File)

1.3.1.9 Marketed by:

**M/S. GREENLIFE PHARMACEUTICALS
LTD.,
35A, ASSOCIATION AVENUE, ILUPEJU,
LAGOS, NIGERIA.,**

1.3.1.10 Manufactured by:

**MCW HEALTHCARE PVT LTD.
236, Sector – E, Industrial Area,
Sanwer Road, Indore (M.P)**
