1.3.1

Summary Of Product Characteristics (SPC)

1.3.1 Product information for health professionals

1.3.1.1Invented 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 Gel U.S.P)..... 360mg

Magnesium Hydroxide USP .....100 mg

Simethicone USP .....125 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 Gel U.S.P)..... 360mg

Magnesium Hydroxide USP .....100 mg

Simethicone USP .....125 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

1.3.1.6.1Therapeutic 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.

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 anemiaor 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

REASTOCID SUSPENSION should not be taken simultaneously with other medicines as they mayinterfere 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, H_2 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 overdosage.

Tetracycline:

Because of the aluminium content, REASTOCID SUSPENSION should not be concomitantlyadministered 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.

1.3.1.6.6 PREGNANCY AND LACTATION

The safety of REASTOCID SUSPENSION in pregnancy has not been

established.Pregnancy:

There are no available data on REASTOCID SUSPENSION use in pregnant women. No conclusions canbe drawn regarding whether or not REASTOCID SUSPENSION is safe for use during pregnancy. REASTOCID SUSPENSION should be used during pregnancy only if the potential benefits to the motheroutweigh the potential risks, including those to the feotus.

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 (≥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.

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:

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 antiflatulents, ATC Code: A02AF02

Dried aluminium hydroxide gel - antacid
Magnesium Hydroxide - antacid
Simeticone - antifoaming agent/antiflatulent

REASTOCID SUSPENSION is a balanced mixture of two antacids and an antiflatulent/antifoaming agentsimeticone. 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 effectis 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

Sr. No.	Name of Ingredients	Specification
01.	Sorbitol Solution 70%	BP
02.	Methyl Paraben Sodium	BP
0.3	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.

1.3.1.9 Manufactured by:

REAGAN REMEDIES LTD
24, Musa Ya'Adua Drive,
Owerri, Imo State.