For the use only of Registered Medical Practitioner

1. Generic Name and Brand Name

Aluminium, Magnesium and Simethicone Oral Suspension I.P.
Famtac® Gel

2. Qualitative and Quantitative Composition:

Each 10 ml contains:
Dried Aluminium Hydroxide Gel I.P. 250 mg
Eq. to Aluminium Hydroxide 191.25 mg
Magnesium Hydroxide I.P. 250 mg
Activated Dimethicone (Simethicone) I.P. 50 mg
(added as Simethicone Emulsion USP 30%)
In Flavoured Base
Colour: Erythrosine

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

For the treatment of Heartburn, Flatulence and Dyspepsia.

4.2 Posology and method of administration

Posology
Adults: 2 teaspoonfuls (10ml) after meals and at bedtime or as required

Method of Administration:

4.3 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.

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.

4.5 Drug Interactions

- It 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 sulfonate: 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).
- Concomitant use of aluminium products with quinidines may increase the serum levels of quinidine and lead to quinidine overdosage.
- Because of the aluminium content, it should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.
- Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.
- Urine alkalinization secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been seen.

4.6 Use in special populations (Pregnancy, Nursing woman, Pediatric use, Geriatric use)

The safety in pregnancy has not been established.

4.7 Effects on ability to drive and use machines

None stated.

4.8 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:
Frequency 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
Injury, poisoning and procedural complications:
Frequency not known: Hyperaluminemia (related to Aluminium 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 which may result in increased bone resorption hypercalciuria, osteomalacia

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, 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 Mechanism of action

It is a balanced mixture of two antacids and an anti-flatulent/antifoaming agent simethicone. 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 Pharmacodynamic Properties

- **Aluminum Hydroxid**e: Following oral administration, aluminum hydroxide is slowly solubilized in the stomach and reacts with hydrochloric acid to produce aluminum chloride and water. This chemical reaction neutralizes gastric acid secretions and increases the gastric pH. The increase in gastric pH inhibits the proteolytic action of pepsin, an effect that is particularly important in patients with peptic ulcer disease. The increased pH and decreased pepsin production helps in the healing of peptic ulcers. While gastric acids are neutralized, the actual secretion of acid is not affected. The chloride salt of aluminum

produced in the stomach reacts with bicarbonate in the small intestine to minimize the risk of systemic alkalosis. Compared with magnesium hydroxide, aluminum hydroxide reacts slowly with bicarbonate because it dissolves slowly in the stomach, which adds to its longer duration of action. In the management of esophageal reflux, the increase in gastric pH produced by antacids, including aluminum hydroxide, causes an increase in the lower esophageal sphincter pressure. This increased pressure minimizes the amount of reflux to the esophagus.

- **Magnesium Hydroxide**: Magnesium hydroxide rapidly reacts with gastric acid to form water and magnesium chloride, which neutralizes gastric acid and increases the gastric pH. The increase in gastric pH inhibits the proteolytic action of pepsin, an effect that is particularly important in patients with peptic ulcer disease. The increased pH and decreased pepsin production help in the healing of peptic ulcers. While gastric acids are neutralized, the actual secretion of acid is not affected. In the management of esophageal reflux, the increase in gastric pH produced by antacids, including magnesium hydroxide, causes an increase in the lower esophageal sphincter pressure. This increased pressure minimizes the amount of reflux to the esophagus. When used as an antacid, magnesium hydroxide is often combined with aluminum salts because the constipating effects of aluminum salts counteract the laxative effects of magnesium salts
- **Simethicone:** As an anti-flatulent, simethicone has been shown in vitro to disperse and prevent the formation of mucus-surrounded gas pockets in the GI tract. Changing the surface tension of the gas bubble prevents these pockets. The gas bubbles coalesce and are more quickly eliminated by flatus, belching, oral absorption into the bloodstream. These actions in vivo have not been clearly established. Additionally, simethicone exhibits in vitro activity against Helicobacter pylori.

5.3 Pharmacokinetic properties

- Aluminum Hydroxide: Aluminum hydroxide is slowly solubilized in the stomach and reacts with hydrochloric acid in the stomach to produce aluminum chloride and water. About 17-30% of the resulting aluminum chloride is absorbed and is rapidly excreted by the kidneys in patients with normal renal function. In the small intestine, aluminum chloride is rapidly converted to insoluble, poorly absorbed, basic aluminum salts. Aluminum also combines with dietary phosphate in the intestine forming insoluble, nonabsorbable aluminum phosphate which is excreted in the feces.
- Magnesium Hydroxide: In the stomach magnesium hydroxide reacts with hydrochloric acid to form magnesium chloride and water. Approximately 15-30% of the magnesium chloride is absorbed and rapidly excreted by the kidneys in patients with normal renal function. Any magnesium hydroxide that is not converted to magnesium chloride is subsequently changed in the small intestine to soluble but poorly absorbed salts. The magnesium that is not absorbed remains in the GI tract and is excreted in the feces.
- Simethicone: Simethicone is physiologically inert and not systemically absorbed. Simethicone is not known to interfere with gastric secretion or nutrient absorption.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

There are no pre-clinical data of relevance to the prescriber

7. Description

Pink coloured viscous suspension with peppermint flavour. Filled in clear, transparent pet bottle having silver coloured ROPP cap with 'Abbott' logo on the top of cap in black colour with EP wad inside the cap.

8. Pharmaceutical particulars

8.1 Incompatibilities

NA

8.2 Shelf Life

Refer Pack

8.3 Packaging Information & handling instructions

Refer Pack

8.4 Storage condition

Refer Pack

9. Patient Counseling Information

- Famtac Gel is used for treatment of symptoms of hyperacidity.
- Heartburn and food reflux may be induced by changes in the diet (sour or spicy food, alcohol, etc.), as well as by some medicines (acetylsalicylic acid, anti-inflammatory drugs, etc.). Ask a doctor for advice, if necessary.
- To reduce the above-mentioned symptoms, follow these instructions:
    - do not eat large amounts of fatty food at once;
    - avoid chocolate, spices, fruit juice, carbonated drinks;
    - eat varied foods;
    - watch your weight, be physically active;
    - do not perform strenuous activities immediately after a meal;
    - Avoid excessive alcohol or cigarette consumption

10. Details of manufacturer

Refer Pack for manufacturer details.

Marketed by:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 &
11 to 13 Ground Floor, 101 to 106 & 111 to 116
First Floor, 201 to 206 & 211 to 216 2nd Floor,
Pimplas, Dist. Thane, Bhiwandi - 421 302,
Maharashtra, India.

11. Details of permission or licence number
Refer Pack for Permission/License details

12. Date of revision
Version No. 2.0, dated 26-Sep-25

For Product Complaints/Adverse events or Queries please write to **webmasterindia@abbott.com**