For use of a Registered Medical Practitioner only

1. Generic Name and Brand Name

Aluminium, Magnesium and Simethicone Oral Suspension I.P.
Digene® PRO

2. Qualitative and Quantitative Composition:

Each 5 ml of suspension contains:
Dried Aluminium Hydroxide Gel I.P..400 mg
(added as paste)
Magnesium Hydroxide I.P……..400 mg
(added as paste)
Simethicone I.P……50 mg
In a flavoured sugar-free base
Colour: Sunset Yellow FCF

3. Dosage Form & strength

Refer section 1 & 2

4. Clinical particulars

4.1 Therapeutic indication

For symptomatic relief of Flatulence, Hyperacidity, Dyspepsia, Heart burn, Gastritis, Gaseous distension.

4.2 Posology and method of administration

Adults: 10 ml, 2 to 3 times a day, to be taken after meals and at bedtime or as advised by the Physician.

4.3 Contraindications

It should not be used in patients who are hypersensitive to any of the active substances, patients with chronic renal disease and dialysis because Magnesium retention may occur in such patients & also may cause hypophosphataemia.

4.4 Special warnings and precautions for use

Aluminium Hydroxide may cause constipation & Magnesium Hydroxide 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. In patients with renal impairment, plasma levels of both Aluminium & Magnesium increase. In these patients, a long-term exposure to high doses of Aluminium and Magnesium salts may lead to dementia, microcytic anemia.

Aluminium Hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. In young children the use of Magnesium Hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

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. Levothyroxine may also bind to simethicone which may delay or reduce the absorption of levothyroxine. Urine alkalinisation 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 of this aluminium Hydroxide, magnesium hydroxide and simethicone suspension in pregnancy has not been established.

Pregnancy:

There are no well-controlled studies to show safety in pregnant women, and use in pregnancy should be based on assessment of the risk/benefit ratio.

Lactation:

The following have been established for the ingredients used individually:

Although small amounts of aluminium are excreted in human breast milk, aluminium hydroxide has limited maternal absorption and is not concentrated in human milk. Magnesium-containing emulsions administered orally to mothers did not affect the stools of breast-feeding infants.

Simethicone: Use in lactation should be based on assessment of the risk/benefit ratio.

4.7 Effects on ability to drive and use machines

None reported.

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.

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 Hydroxide 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 antacids and an anti-flatulent/antifoaming agent. 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

Aluminium Hydroxide: Is partly Aluminium Hydroxide and partly Aluminium Oxide hydrated to a variable extent. It reacts with Hydrochloric Acid in stomach forming Aluminium Chloride. Aluminium Hydroxide is insoluble; hence the fraction of excess remains in the stomach shall exert a sustained effect. Gastric pH does not rise above the level which will inhibit conversion of pepsinogen to pepsin. It is also a demulscent. Wet particles of Aluminium Hydroxide are somewhat adhesive and this helps in forming the protective coat over the ulcer.

Magnesium Hydroxide: Reacts with gastric Hydrochloric Acid forming Magnesium Chloride. It is also a long-acting antacid with high acid neutralizing capacity.

Simethicone: Is an anti-foaming agent. It acts by changing the surface tension of gas bubbles thereby causing them to coalesce, thus facilitating the elimination of gas. Accordingly, it provides relief from abdominal distension and dyspepsia.

5.3 Pharmacokinetic properties

The absorption of Aluminium and Magnesium from antacids is small. Aluminium Hydroxide is slowly converted to Aluminium Chloride in the stomach. Some absorption of soluble Aluminium salts occurs in the gastro-intestinal tract with urinary excretion. Any absorbed Magnesium is likewise excreted in the urine. Aluminium containing antacids should not be administered to patients with renal impairment where increased plasma concentration may occur. Simethicone is physiologically inert and not systemically absorbed, also not metabolize & is excreted unchanged in the feces.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

There is no pre-clinical data of relevance to the prescriber.

7. Description

A orange Coloured, Viscous Suspension with Orange flavour.

8. Pharmaceutical particulars

8.1 Incompatibilities

None

8.2 Shelf Life

Refer Pack

8.3 Packaging Information

200 ml bottle

8.4 Storage condition & Handling instructions

Store at a temperature not exceeding 30°C.

Shake the bottle before use.

9. Patient Counseling Information

- 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

Manufactured by:

Abbott India Limited
At: Village Bhatauli Khurd,
P.O. Baddi - 173 205, Dist. Solan,
Himachal Pradesh, India.

11. Details of permission or licence number with date

Mfg. Lic. No. L/12/1107/MNB, dated 24-Sep-24

12. Date of revision

Version: 1.0 Dated 18-Aug-26

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