For use of a Registered Medical Practitioner only

1. **Generic Name and Brand Name**
   Aluminium, Magnesium and Simethicone Oral Suspension I.P.
   DIGENE® INSTA
   ON THE GO

2. **Qualitative and Quantitative Composition:**
   Each 5 ml of suspension contains:
   Dried Aluminium Hydroxide Gel I. P. 400mg
   (added as paste)
   Magnesium Hydroxide I. P. 400mg
   (added as paste)
   Simethicone I. P. 50mg
   In a flavored sugar free base
   Colour: Carmoisine

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: Take 1 shot (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)

Because of the limited maternal absorption, when used as recommended, minimal amounts, if any, of Aluminium Hydroxide and Magnesium Hydroxide combinations are expected to be excreted into breast milk. 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. There is limited or no data available of its use in pregnancy.

4.7. Effects on ability to drive and use machines

None reported.

4.8. Undesirable effects

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. Magnesium Aluminium Silicate Hydrate reacts with acid in the stomach to increase the pH.

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

7. Description

DIGENE INSTA ON THE GO is supplied for oral administration, as a suspension of Aluminium, Magnesium and Simethicone. Each 5 ml of suspension contains Dried Aluminium Hydroxide Gel 400 mg (added as paste), Magnesium Hydroxide 400 mg (added as paste) & Simethicone 50 mg.

8. Pharmaceutical particulars

8.1. Incompatibilities

None

8.2. Shelf Life

Refer Pack

8.3. Packaging Information

Refer Pack

8.4. Storage condition & Handling instructions

Refer Pack

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

Refer Pack for manufacturer details

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11. Details of permission or licence number with date

Refer Pack for Permission/License details

12. Date of revision

Version: 1.0, Dated: 3-Dec-24

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