

Size : 165x120 mm

15/02/2023
Add. Revision Date

**ALUMINIUM HYDROXIDE+
MAGNESIUM TRISILICATE+
SIMETHICONE**

GASCID
Chewable Tablet
ANTACID, ANTI-FLATULENT



COMPOSITION:

Each uncoated chewable tablet contains:
Dried Aluminium Hydroxide BP 250 mg
Magnesium Trisilicate BP 250 mg
Simeticone BP 25 mg

Description: Pink, coloured, round, flat, uncoated chewable tablets, debossed with "GASCID" on one side and plain on other side.

PHARMACOLOGY:

Dried aluminium hydroxide gel - antacid
Magnesium Trisilicate - antacid
Simeticone - Antifoaming agent/antiflatulent
The antacids are balanced such that gastrointestinal side effects (constipation and diarrhoea) are minimal.

PHARMACOKINETICS:

None- Stated

INDICATION:

The symptomatic relief of Dyspepsia, Heartburn & Flatulence.

DOSAGE AND ADMINISTRATION:

Adults (including elderly persons): 1-2 tablets well chewed, four times a day.

To be taken 20 minutes to 1 hour after meals and at bedtime, or as required.

Children: Not recommended

CONTRAINDICATION:

Should not be used in patients who are severely debilitated or suffering from kidney failure.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Hypersensitivity to the active ingredients or to any of the excipients.

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-phosphorus 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 dementia, microcytic anemia.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not

take this medicine.

Unsuitable for phenylketonurics

PREGNANCY:

The safety of Gascid Chewable Tablets in pregnancy has not been established.

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 effects 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

ADVERSE 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

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.

DRUG INTERACTION:

Gascid Chewable Tablets 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,

cefepodoxime, levothyroxine, rosuvastatin.

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 risk 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).

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

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

Jauhkan daripada capaian kanak-kanak.

Keep out of reach of children.

AVAILABILITY:

10 tablets packed in Alu-Pvc blisters. Such 10 blisters packed in unit carton along with package insert.

Date of Revision: 15-02-2023

Product Registration Holder:

Healol Pharmaceuticals Sdn.Bhd

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XL

Manufactured by :

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