SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gastrone Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Aluminium Hydroxide USP 250mg
Magnesium Hydroxide USP 250mg
Simethicone USP 50mg
For a full list of excipients see section **6.1**

3. PHARMACEUTICAL FORM

Chewable tablet (Solid)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gastrone is indicated for the relief of the symptoms of peptic ulcer, gastric hyper acidity, reflux oesophagitis, heartburn and postoperative gas pain. It is also used in the treatment of, indigestion, flatulence and dyspepsia

4.2 Posology and method of administration

For oral administration. Tablets should be chewed before swallowing;
Adults and children over 12 years: Two tablets to be taken 3 to 4 times daily or as directed by the physician.
Children 6-12 years: Half the adult dose

4.3 Contraindications

Use in severely debilitated patients or in those suffering from kidney failure.
Use in patients who are hypersensitive to the active ingredients or to any of the excipients.

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 risks such as those with renal impairment, infants less than 2years, 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 or in infants less than 2years, may lead to phosphate depletion (due to Aluminiumphosphate 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.

Magnesium salts may cause central nervous depression in the presence of renal insufficiency and should be used with extreme caution in patients with kidney disease.

Inpatients with renal impairment, plasma levels of both Aluminium and Magnesium increase. In these patients, along term exposure to high doses of Aluminium and Magnesium salts may lead to encephalopathy, dementia, microcyticanemia or worsen dialysis-induced osteomalacia.

The prolonged use of antacids in patients with renal failure should be avoided.

Care should be observed if used by diabetics because of the sugar content in the tablet.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis because it has been shown that Aluminium may be involved in porphyrin metabolism abnormalities.

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase–isomaltase insufficiency should not take this medicine.

Prolonged use with antacids may mask symptoms of more serious diseases, such as gastrointestinal ulceration or cancer.

4.5 Interaction with other medicinal products and other forms of interaction

Aluminium hydroxide may form complexes with certain drugs, e.g. tetracyclines, digoxin and vitamins, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.

Concomitant use with quinidines may increase the serum levels of quinidine and lead to quinidine and lead to quinidine overdosage.

Aluminium-containing antacids may prevent the proper absorption of H_2 antagonists, atenolol, cefdinir, cefpodoxime chloroquine, cyclines, diflunisal, digoxin, diphosphonates, ethambutol, fluoroquinolones, sodiumfluorure, glucorticoids, indometacine, isoniazide, kayexalate, ketoconazole, lincosamides, metoprolol, neuroleptics phenothiazines, penicillamine, propranolol, iron salts.

Staggering the administration times of the interacting drug and the antacid by at least 2hours (4hours for the fluoroquinolones) will often help avoid undesirable drug interactions.

Polystyrene sulfonate (Kayexalate)

Caution is advised when used concomitantly with polystyrene sulfonate (Kayexalate) due to the potential risks of reduced effectiveness of the rest in binding Potassium,of metabolic alkalosis inpatients 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.

4.6 Pregnancy and lactation

The use of Gastrone should be avoided during the first trimester of pregnancy.

Due to limited maternal absorption when used as recommended, Aluminium hydroxide and Magnesium salts combinations are considered as compatible with lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Side effects are uncommon at recommended doses

Immune system disorders

Frequency unknown: hypersensitivity reactions, such as pruritus, urticaria, angioedema and anaphylactic reactions

Gastrointestinal disorders

Uncommon: diarrhea or constipation

Metabolism and nutrition disorders

Frequency unknown:

-hypermagnesemia,

-hyperaluminemia,

- hypophosphatemia, in prolonged use or at high doses or even normal doses of the product in patients with low phosphorus diets or in infants less than 2 years, which may result in increased bone resorption, hypercalciuria, osteomalacia.

4.9 Overdose

Reported symptoms of acute overdose with Aluminium hydroxide and magnesium salts combination include diarrhea, abdominal pain, vomiting. Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk.

MANAGEMENT

Aluminium and Magnesium are eliminated through urinary route; treatment of acute overdose consists of rehydration, forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary. Serious symptoms are unlikely following over dosage

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Gastrone is a mixture of two antacids and simethicone: Aluminium hydroxide is a slow-acting antacid and Magnesium hydroxide is a fast-acting one. The two are frequently

combined in antacids mixtures. Aluminium hydroxide on its own is astringent and may cause constipation. This effect is balanced by the effect of Magnesium hydroxide, which, in common with other Magnesium salts, may cause diarrhoea. Simethicone is a surface-active agent included to disperse foam. This reduces gastro oesophageal reflux. It does not have antacid properties.

5.2 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.

5.3 Preclinical safety data

Not relevant

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose, gelatin, sucrose, methylparaben, aerosil, talc, magnesium stearate and peppermint oil

6.2 Incompatibilities

Not Applicable

6.3 Shelf life Two (2) years

6.4 Special precautions for storage

Store below 30°C. Keep out of reach and sight of children. Protect from light.

6.5 Nature and contents of container

Aluminium/ poly (LDPE) foil as primary packaging and paper carton as secondary packaging.

7.0 MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Ernest Chemists Limited
Ring Road Central
P. O. Box 3345, Accra
Ghana

8 MARKETING AUTHORIZATION NUMBER

FDB/SD.175-5286

9 DATE OF FIRST AUTHORIZATION OR RENEWAL

11/30/2022

10 DATE OF REVISION OF THE TEXT

08/2025