SUMMARY OF PRODUCT CHARACTERISTICS

GESTID TABLETS

1. NAME OF THE MEDICINAL PRODUCT

GESTID TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:
Dried Aluminium Hydroxide BP…….300 mg
Magnesium Trisilicate BP…….50 mg
Magnesium Hydroxide USP…….…….25 mg
Simethicone USP……...10 mg

For the full list of excipients, see **section 6.1.**

3. PHARMACEUTICAL FORM

Chewable tablets

Physical Description:
Light yellow, round, flat tablets with beveled edges, debossed with GESTID on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications [1, 2, 3]

GESTID TABLETS are indicated for the relief from indigestion, acidity, dyspepsia, heart burn, and flatulence.

4.2 Posology and method of administration [1, 2, 3]

Adults and children over 12 years: One or two tablets to be sucked or chewed after meals, at bedtime or whenever discomfort is felt.

Children 6 to 12 years: One tablet to be sucked or chewed after meals, at bedtime or whenever discomfort is felt.

Children under 6 years: Not recommended.
Elderly: There is no need for dosage reduction in the elderly.

4.3 Contraindications [1, 3]

GESTID TABLETS are contraindicated in:

- Patients with hypersensitivity to the active ingredients or to any of the excipients
- Severely debilitated patients
- Patients with kidney failure
- Hypophosphatemia
- Rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

4.4 Special warnings and precautions for use [1, 2, 3, 4, 5]

Keep all medicines out of reach of children.

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 encephalopathy, dementia and microcytic anaemia or worsen dialysis-induced osteomalacia.

Care is necessary in patients with chronic renal impairment: osteomalacia or adynamic bone disease, encephalopathy, dementia, and microcytic hypochromic anaemia have been associated with aluminium accumulation in such patients given large doses of aluminium hydroxide.

Aluminium hydroxide may be unsafe in patients with porphyria undergoing haemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

There is little evidence that aluminium containing antacids are a risk factor for Alzheimer's disease.

Hypermagnesaemia may occur, usually in patients with renal impairment or patient with normal renal function but bowel obstruction.

Care should be exercised in treating diabetic patients.

Concurrent use of antacid may antagonize the effect of pentagastrin and histamine in the evaluation of gastric acid secretory function, administration of antacid is not recommended on the morning of the test.

GESTID TABLETS contains sucrose
This medicine contains sucrose, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

GESTID TABLETS contains tartrazine
This medicine contains colouring agent tartrazine, this may cause allergic reactions.

GESTID TABLETS contains sodium
The content of sodium should also be taken into account by patients on a sodium controlled diet. Each tablet also contains 21mg (0.91Meq) of sodium.

4.5 Interaction with other medicinal products and other forms of interaction [1, 3, 4, 5, 6]

Effects on absorption
Aluminium and magnesium hydroxide compounds used as antacids interact with many other drugs, both by alterations in gastric pH and emptying, and by direct adsorption and formation of complexes that are not absorbed. Interactions can be minimised by giving the aluminium compound and any other medication 2 to 3 hours apart.

This product may interfere with the absorption of tetracyclines, vitamins, quinolones, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H_2 antagonists, atenolol, cyclines, diflunisal,

digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine, propranolol phenothiazines and iron salts when given concomitantly.

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

Absorption of fluoroquinolones may be reduced resulting in lower serum and urine concentrations; therefore, concurrent use is not recommended. Ciprofloxacin and lomefloxacin is recommended to be taken 2 hours before or 6 hours after the antacid. Norfloxacin and ofloxacin is recommended to be taken 2 hours before or after the antacid.

Levothyroxine
Levothyroxine may bind to simethicone which may delay or reduce the absorption of levothyroxine. Absorption of levothyroxine may be impaired if this product is given concurrently to infants treated for thyroid disorders.

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).

Tetracycline:
Because of the aluminium content, **GESTID TABLETS** should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

Prolonged use of antacids may decrease absorption of folic acid and Iron salts. Patient should be advised to take antacids at least 2 hours after folic acid.

Absorption of histamine-H_2 receptor antagonists may be decreased if administered concurrently with antacids. Patient should be advised not to take antacids within ½ to 1 hour of histamine H2 receptor antagonists.

Concurrent use of chenoidiol with aluminium containing antacids may results in binding of chenodiol, thus decreasing its absorption.

Citrates
Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

Other effects
Antacids may alkalinise the urine and counteract the effect of urinary acidifiers (i.e., ammonium chloride, ascorbic acid). Frequent use of antacids should be avoided by patients receiving therapy to acidify the urine.

Alkalization of urine may reduce the solubility of ciprofloxacin and norfloxacin in the urine especially when the urinary pH exceeds 7.0. Patients should be observed for signs of crystalluria and neurotoxicity.

Urinary excretion of amphetamines and quinidine may be inhibited when these medications are used concurrently with antacids in doses that cause the urine to become alkaline. Dosage adjustment may be needed when therapy with antacids is initiated, discontinued or if dosage is changed.

Urine alkalinisation secondary to administration of magnesium hydroxide may modify excretion of some drugs; thus, increased excretion of salicylates has been reported.

Laboratory test interactions
Prior administration of aluminium containing antacids may decrease stomach and bladder uptake of sodium pertchnetate Tc 99m.

4.6 Fertility, Pregnancy and lactation [3]

Pregnancy
The safety of Gestid Tablets in pregnancy has not been evaluated.

There are no adequate human data from the use of aluminium hydroxide and magnesium hydroxide in pregnant women. No conclusions can be drawn regarding whether or not Gestid Tablets is safe for use during pregnancy. Gestid Tablets should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

Lactation

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 simethicone is negligible.

4.8 Undesirable effects [1, 5]

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: Hypermagnesaemia, 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, and osteomalacia.

Large doses of aluminium hydroxide can cause intestinal obstruction.

Renal calculi with magnesium trisilicate

The formation of renal calculi containing silica is unusual, but has been reported in a small number of patients. In most of these reported cases, stone formation was attributed to the prolonged, and sometimes excessive, intake of antacids that contained magnesium trisilicate.

4.9 Overdose [1, 2, 3]

Serious symptoms are unlikely following overdosage.

Symptoms of overdosage include nausea, vomiting, gastrointestinal irritation, abdominal pain and diarrhoea/constipation. Abdominal distension may occur. Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk. Treatment should be symptomatic and supportive.

Treatment of aluminium and magnesium overdose: aluminium and magnesium are eliminated through urinary route; consider administration of IV calcium gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICAL PROPERTIES [1, 4, 5, 6]

5.1 Pharmacodynamic properties

Antacids provide rapid control of acidity by neutralizing the gastric acid. This action results in increased pH of stomach contents, thus providing the relief of the symptoms of the hyperacidity. Acid concentration within the lumen of oesophagus is also reduced, resulting in an increased intraoesophageal pH. Antacids also reduce pepsin activity.

Dried aluminium hydroxide, magnesium hydroxide and magnesium trisilicate are used as antacids. Aluminium hydroxide has constipating effects whereas magnesium hydroxide and magnesium trisilicate has laxative effects. These are given in combination to counteract these effects.

Simethicone is used for the relief for the flatulence and abdominal discomfort. It is a gastric defoaming agent that works by altering the elasticity of interfaces of mucus-embedded bubbles in the gastrointestinal tract. The gas bubbles are thus broken down or coalesced and in this form gas is more easily eliminated through eructation or passing flatus.

5.2 Pharmacokinetic properties

Aluminium hydroxide, given orally slowly reacts with the hydrochloric acid in the stomach to form soluble aluminium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of aluminium hydroxide to react and may increase the amount of aluminium chloride

formed. Absorbed aluminium is eliminated in the urine and patients with renal failure are therefore at particular risk of accumulation. The aluminium compounds remaining in the gastrointestinal tract, which account for most of the dose form insoluble poorly, absorbed salts, which are excreted in the faeces.

Magnesium, given by mouth, reacts relatively rapidly with hydrochloric acid in the stomach to form magnesium chloride and water. Approximately 10% of the magnesium is slowly absorbed from the gastrointestinal tract and excreted in the urine; the rest is excreted via the faeces.

Simethicone is not absorbed from the gastrointestinal tract.

5.3 Preclinical safety data [6, 7]

Aluminium and magnesium salts have not been reported to have any mutagenic potential or carcinogenicity. There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the prescribing information.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients: Maize starch, Tartrazine lake, Chloroform, Povidone, Sucrose, Sodium chloride, Disodium edetate, Sodium benzoate, Purified water, Magnesium stearate, Mentha oil and Levomenthol

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30ºC.
Keep all medicines out of the reach of children.

6.5 Nature and contents of container

Gestid Tablets are available as Al-Foil laminated pack of 5x4’s.

6.6 Special precautions for disposal and other handling

Not Applicable

7. MARKETING AUTHORISATION HOLDER

Ranbaxy Nigeria limited

8. MARKETING AUTHORISATION NUMBER

04-2195

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

15-02-2001

10. DATE OF REVISION OF THE TEXT

December 2021

REFERENCES

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