

For the Use of a Registered Medical Practitioner only

PRESCRIBING INFORMATION

# Gestid<sup>Plus</sup> Suspension

(Calcium Carbonate, Sodium Bicarbonate, Dried Aluminium Hydroxide,  
Magnesium Hydroxide and Simethicone Suspension)

## COMPOSITION

### Gestid Plus Suspension (Lemon Mint)

#### Each 5 ml contains:

Calcium Carbonate BP .....125 mg  
Sodium Bicarbonate BP .....125 mg  
Dried Aluminium hydroxide BP .....100 mg  
Magnesium Hydroxide BP .....100 mg  
Simethicone USP .....20 mg  
Saccharin Sodium BP .....5 mg  
Colours: Quinoline Yellow  
Contains Alginic acid, flavours in a sugar-free base q.s.

### Gestid Plus Suspension (Ginger aniseed mint)

#### Each 5 ml contains:

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Sodium Bicarbonate BP .....125 mg  
Dried Aluminium hydroxide BP .....100 mg  
Magnesium Hydroxide BP .....100 mg  
Simethicone USP .....20 mg  
Saccharin Sodium BP .....5 mg  
Colours: Quinoline Yellow & Brilliant Blue  
Contains Alginic acid, flavours in a sugar-free base q.s.

## DESCRIPTION<sup>1,2,3,4,5,6</sup>

Gestid Plus Suspension contains the antacids calcium carbonate, sodium bicarbonate, dried aluminum hydroxide, magnesium hydroxide, the antiflatulent agent/surfactant simethicone, and flavoring agent and non-nutritive sweetener saccharin sodium.

**Calcium carbonate:** The molecular formula is CaCO<sub>3</sub>, with a molecular weight of 100.086900 g/mol.

**Sodium Bicarbonate:** It is chemically sodium hydrogen carbonate. The molecular formula is NaHCO<sub>3</sub>, with a molecular weight of 84.006610 g/mol.

**Dried aluminium hydroxide:** It is chemically aluminum trihydrate. The molecular formula is AlH<sub>3</sub>O<sub>3</sub>, with a molecular weight of 81.027378.

**Magnesium Hydroxide:** It has the molecular formula Mg(OH)<sub>2</sub> and molecular weight 58.32.

**Simethicone:** Simethicone is a poly (dimethylsiloxane) which is a polymer of 200-350 units of dimethylsiloxane, along with added silica gel.

**Saccharin sodium:** It is a flavoring agent and non-nutritive sweetener.

## INDICATIONS<sup>16,12</sup>

Gestid Plus Suspension is indicated for the relief from indigestion, acidity, dyspepsia, heart burn and flatulence.

## DOSE AND METHOD OF ADMINISTRATION<sup>16,12,13</sup>

**Adults and children over 12 years:**  
10 ml to 20 ml after meals and at bedtime or as required.

### Children below 12 years:

An appropriate proportion of the adult dose should be given only on medical advice.

### Elderly:

There is no need for dosage reduction in the elderly.

## USE IN SPECIAL POPULATIONS<sup>8,19</sup>

### • Pregnancy

Safety of Gestid Plus Suspension in pregnancy has not been established. Caution should be exercised when prescribed to pregnant women.

### • Lactation

There is no data of Gestid Plus Suspension in lactation, should be given only on medical advice.

## CONTRAINDICATIONS<sup>16,12</sup>

Gestid Plus Suspension is contraindicated in:

- Patients with hypersensitivity to any of the ingredients
- Severely debilitated patients
- Patients with kidney failure
- Hypophosphatemia

## WARNINGS AND PRECAUTIONS<sup>8,10,12</sup>

### Dried aluminium hydroxide and magnesium hydroxide:

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 osteomalacia or encephalopathy with seizures and dementia, bone disease, and microcytic anaemia.

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

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.

### Sodium Bicarbonate

Bicarbonate should not generally be given to patients with metabolic or respiratory alkalosis, hypocalcaemia, or hypochlorhydria. During treatment of acidosis, frequent monitoring of serum-electrolyte concentrations and acid-base status is essential.

Sodium-containing salts should be given extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension, eclampsia, or aldosteronism.

### Calcium carbonate

Care needs to be taken in treating patients with hypercalcaemia, nephrocalcinosis, and recurrent calcium containing renal calculi.

Gestid Plus Suspension contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine

## DRUG INTERACTIONS<sup>8,10,11,12</sup>

Aluminium 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, iron salt, chloroquine, penicillamine, phenothiazines and quinolone antibacterials when given concomitantly.

The absorption of aluminium from the gastrointestinal tract may be enhanced if aluminium compounds are taken with citrates or ascorbic acid especially in patients with renal impairment.

Omeprazole significantly reduces the absorption of calcium from a calcium carbonate supplement given on an empty stomach.

Thiazide diuretics increase the risk of the milk-alkali syndrome in patients taking moderately large doses of calcium carbonate.

Sodium bicarbonate enhances lithium excretion. Concurrent use is not recommended.

Alkalinisation of the urine leads to increased renal clearance of acidic drugs such as salicylates, tetracyclines, and barbiturates.

## UNDESIRABLE EFFECTS<sup>16,12</sup>

Patients sensitive to any of the ingredients may develop allergic manifestations such as urticaria or bronchospasm, anaphylactic or anaphylactoid reactions.

### Dried aluminium hydroxide:

It is an astringent and may cause constipation. Large doses can cause intestinal obstruction. Excessive doses, or even normal doses in patients with low phosphate diets, may lead to phosphate depletion accompanied by increased bone resorption and hypercalcaemia with the risk of osteomalacia or rickets.

### Magnesium hydroxide:

There have been reports of hypermagnesaemia and diarrhoea.

### Calcium carbonate:

Calcium carbonate may occasionally cause constipation. Flatulence from released carbon dioxide may occur in some patients. Ingestion of large quantities of calcium carbonate may cause alkalosis, hypercalcaemia, acid rebound, milk alkali syndrome or constipation. These usually occur following larger than recommended dosages.

High doses or prolonged use may lead to gastric hypersecretion and acid rebound. Calcium carbonate can cause hypercalcaemia, particularly in patients with renal impairment or after high doses. Alkalosis may also occur as a result of the carbonate anion. There have been rare reports of the milk-alkali syndrome, and tissue calcification

### Sodium bicarbonate:

Excessive use of sodium bicarbonate at higher doses than recommended may lead to electrolyte imbalance, hypernatraemia, hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients. Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality. Sodium bicarbonate given orally can cause stomach cramps, belching, and flatulence.

### Simethicone:

Gastrointestinal side effects are uncommon.

## OVERDOSE<sup>16,12</sup>

Serious symptoms are unlikely following overdosage.

Symptoms of overdosage include nausea, vomiting, gastrointestinal irritation, diarrhoea/constipation. Treatment should be symptomatic and supportive.

## PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES<sup>12</sup>

### • Pharmacodynamics

Dried aluminium hydroxide and magnesium hydroxide are used as antacids. Aluminium hydroxide has constipating effects and magnesium hydroxide has laxative effects. These are given in combination to counteract their effects. Calcium carbonate is an antacid. It rapidly reacts with gastric acid to produce calcium chloride.

Sodium bicarbonate is a rapid onset, short acting antacid which neutralizes acid secretions in the gastrointestinal tract by reacting with hydrochloric acid to produce sodium chloride. During neutralization

carbon dioxide is released, facilitating erucation which provides a sense of relief.

Simethicone is used for the relief of flatulence and abdominal discomfort.

### • Pharmacokinetics

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 hydroxide, given by mouth, reacts relatively rapidly with hydrochloric acid in the stomach to form magnesium chloride and water. About 30% of the magnesium ions are absorbed from the small intestine. calcium carbonate is converted to calcium chloride by gastric acid. Some of the calcium is absorbed from the intestines but about 85% is reconverted to insoluble calcium salts, such as the carbonate and is excreted in the faeces.

Administration of sodium bicarbonate by mouth causes neutralization of gastric acid with the production of carbon dioxide. Bicarbonate not involved in that reaction is absorbed and in the absence of a deficit of bicarbonate in the plasma, bicarbonate ions re excreted in the urine that is rendered alkaline with an accompanying diuresis.

Simethicone is not absorbed from the gastrointestinal tract.

**STORAGE:** Store below 30°C, away from direct sunlight. Do not freeze.

**Keep all medicines out of reach of children**

**SUPPLY:** Bottle pack of 100 ml and 180 ml.

## REFERENCES

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Information compiled in November, 2010.

### Manufactured By:

**Ranbaxy Nigeria Limited**  
a SUN PHARMA company  
KM 30, LAGOS IBADAN EXPRESSWAY  
MAGBORO, OGUN STATE, NIGERIA



Under Licence From  
**Sun Pharmaceutical**  
Ind. Ltd., India

Black

**Gestid Plus Susp PIL**

**PIL size - 140 x 200 mm**

**Market: Nigeria**

**SPIL/PKGDEV - CG17/Jul/2018-V01, V02**