Summary of Product Characteristics (SmPC)

1. Name of the medicinal product:
GASTRIGEL

1.1 Name of the medicinal product:
Alumina, Magnesia and Simethicone Oral Suspension USP

1.2 Strength:
Each 5 ml contains:
Simethicone Emulsion USP
equivalent to Simethicone: 50 mg
Magnesium Hydroxide USP: 250 mg
Dried Aluminum Hydroxide Gel USP: 250 mg
Equivalent to Aluminum Hydroxide: 191.25 mg
Sorbitol Solution 70 % BP (Non- crystallising): 1.25 gm
Colour : Erythrosine

1.3 Pharmaceutical form:
Suspension; Oral use

2. Qualitative and quantitative composition
Each 5 ml contains:
Simethicone Emulsion USP
equivalent to Simethicone: 50 mg
Magnesium Hydroxide USP: 250 mg
Dried Aluminum Hydroxide Gel USP: 250 mg
Equivalent to Aluminum Hydroxide: 191.25 mg
Sorbitol Solution 70 % BP (Non- crystallising): 1.25 gm
Colour : Erythrosine

3. Pharmaceutical form
Suspension; Oral use

4. Clinical particulars:
4.1 Therapeutic indications:
GASTRIGEL acts as an antacid in dyspepsia and is used for the symptomatic relief of hyperacidity associated with peptic ulceration, gastritis, esophageal reflux with heartburn and gastric hyperacidity.
GASTRIGEL may be of benefit if symptomatic relief could not be obtained with antacid therapy alone.

4.2 Posology and method of administration

1-2 teaspoonful (5-10 ml) 1/2 to 1 hour after each meal or whenever symptoms are pronounced.

Method of Administration: Oral

4.3 Contraindications

Do not use this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline. This medicine should not be given to any patient who has demonstrated a sensitivity to it. The use of aluminium- or magnesium-containing antacids is contra-indicated in patients with symptoms of appendicitis since these medicines may increase the danger of perforation or rupture due to their constipating or laxative effects. The use of aluminium containing antacids (except those containing aluminium phosphate) is contra-indicated in patients with hypophosphataemia due to the phosphate binding properties of aluminium salts.
The use of magnesium-containing antacids is contra-indicated in patients with severe renal function impairment due to increased danger of occurrence of hypermagnesemia.

4.4 Special warnings and precautions for use

In patients with chronic renal failure, hyperaluminaemia may occur. Encephalopathy and dementia may occur in patients with poor renal function or patients on dialysis, due to an increase in plasma concentration of aluminium. Hypophosphataemia may occur with prolonged administration or large doses of aluminium-containing antacids (except aluminium phosphate) especially in patients with an inadequate dietary intake of phosphorus. Laboratory Tests -Serum phosphate levels should be monitored at monthly or bi-monthly intervals in patients on maintenance haemodialysis who are receiving chronic antacid therapy. Use in children -The safety and effectiveness of GASTRIGEL in children has not been established.
Drug Interactions -The rate and / or extent of absorption of many medicines may be increased or decreased. Therefore, medication should not be taken within one to two hours of GASTRIGEL. An incomplete list of substances for which the above statement has been shown to apply includes: tetracycline, iron salts, isoniazid, ethambutol, some anti-muscarinic drugs, benzodiazepines, phenothiazines ranitidine, indomethacin, phenytoin, nitrofurantoin, Vitamin A, fluoride and phosphate. An increase in the plasma level of quinidine and possible toxicity may result it alkalisation of the urine occurs following antacid therapy.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids are known to interfere with the absorption of certain drugs including tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir and cefpodoxime. Aluminium hydroxide and citrates may result in increased aluminium levels, especially in patients with renal impairment.

4.6 Pregnancy and lactation

No clinical data on exposed pregnancies are available. Use of antacids should be avoided in the first trimester of pregnancy. Caution should be exercised when prescribing to pregnant and lactating women. Magnesium is considered compatible with lactation.

4.7 Effects on ability to drive and use machines:

None stated.

4.8 Undesirable effects:

Gastrointestinal side effects are uncommon. However, occasional diarrhoea or constipation may occur if use is excessive.

4.9 Overdose:

Serious symptoms are unlikely following overdose. Discontinue medication and correct fluid deficiency if necessary. Treatment of magnesium overdose: consider administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal deficiency, haemodialysis or peritoneal dialysis is necessary.

5. Pharmacological properties:

5.1 Pharmacodynamics properties:

Simethicone, Alumina gel and magnesium hydroxide react chemically to neutralize or buffer existing quantities of acid, but have no direct effect on its production. This action increases gastric pH. Gastroscopic observations reveal that alumina gel, especially when swallowed undiluted, forms a diffuse coating over the inflamed gastric mucosa for a variable period of time.

5.2 Pharmacokinetic Properties

Studies have shown that a small amount of aluminium from aluminium hydroxide is absorbed from the intestine. Approximately 10% of the magnesium in magnesium hydroxide is absorbed from the intestine.

5.3 Preclinical safety data

Not relevant.

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Ingredients	Specification
1.	Sorbitol solution 70% (non-crystallizing)	BP
2.	Sodium Methyl hydroxy benzoate	BP
3.	Sodium Propyl hydroxy benzoate	BP
4.	Sodium benzoate	BP

5.	Xanthan Gum	BP
6.	Glycerol	BP
7.	Colloidal Anhydrous Silica	BP
8.	Polysorbate-80	BP
9.	Sodium Saccharin	BP
10.	Sucralose	BP
11.	Sodium Hypochloride	BP
12.	Citric Acid Monohydrate	BP
13.	Peppermint 18774 (For Gel)	IH
14.	Levomenthol	BP
15.	Erythrosine Supra	IH
16.	Sodium Citrate	BP
17.	Bronopol	BP
18.	Sodium CMC	BP
19.	Creshmer RH-40	BP
20.	Purified water	BP

6.2 Incompatibilities
Not known

6.3 Shelf life
36 Months (3 Years) from date of manufacturing.

6.4 Special precautions for storage
Store at a temperature below 30°C. Protect from light. Do not freeze.

6.5 Nature and contents of container
200 ml Amber colored glass bottle.
Such one bottle is packed in carton along with measuring cup and insert.

6.6 Special precautions for disposal:
None

7. Registrant:
M/s. BOCHE PHARM NIGERIA LTD
41 B, Iwaya Road, Onike, Yaba, Lagos State, Nigeria.

8. MANUFACTURER
CORAL LABORATORIES LTD.
Plot No. 57 / 1 (16), Bhenslore, Dunetha,
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Website: www.corallab.com

9. Date of revision of the text: NA