1. Name of the medicinal product

NUTRACID

(Dried Aluminium Hydroxide, Magnesium Hydroxide, Simethicone & Sodium Alginate Suspension)

2. Qualitative and quantitative composition

Each 5 ml Contains:
Aluminium Hydroxide Paste Equi. to
Dried Aluminium Hydroxide BP……..125 mg
Magnesium Hydroxide Paste Equi. to
Magnesium Hydroxide BP……250 mg
Simethicone USP…….50 mg
Sodium Alginate BP…….100 mg
Flavoured Syrupy Base……q.s.
Colour: Erythrosine

3. Pharmaceutical form

Suspension

Pink colored flavoured suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NUTRACID used for symptomatic relief of:

1. Dyspepsia.
2. Heartburn.
3. Flatulence

4.2 Posology and method of administration

Adults

5-10ml taken 20 minutes to 1 hour after meals and at bedtime or as required.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5ml t.d.s.

Elderly

The normal adult dose is appropriate.

Method of administration

Oral administration.

4.3 Contraindications

Should not be used in patients who are hypersensitive to any of the active substances or excipients, are severely debilitated or suffering from kidney failure, or hypophosphataemia

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 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-phosphorous 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.

This product contains sorbitol (E420). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains methyl paraben (E218) and propyl paraben (E216); these may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

NUTRACID 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 drags such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine, chlorpromazine, rifampicin, cefdinir, cefpodoxime, 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 risks 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.

4.6 Pregnancy and lactation

The safety of NUTRACID (Suspension) 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 effect on the breastfed newbom/infant are anticipated since the systemic exposure of the breast-feeding woman to aluminium hydroxide, magnesium hydroxide and simeticone is Negligible.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable:
Very common (> 1/10), common (> 1/100 to <1/10), uncommon (>1/1,000 to <1/100), rare (>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
Metabolism and nutrition disorders
Frequency not known:
Hypermagnesemia
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.

4.9 Overdose

Serious symptoms are unlikely following overdosage. 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 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulents,
ATC Code: A02AF02

NUTRACID is a balanced mixture of two antacids and an antiflatulent/antifoaming agent simeticone. The two antacids are magnesium hydroxide which is fast acting and aluminium hydroxide which is a slow acting antacid. The combination produces a fast onset of action and an increase in total buffering time. Aluminium hydroxide on its own is an astringent and may cause constipation. This effect is balanced by the effect of the magnesium hydroxide which is in common with other magnesium salts may cause diarrhoea. Sodium Alginate forms a rigid raft of alginic acid in the stomach reducing gastric reflux. This raft formed is maintained in the stomach for two hours.

5.2 Pharmacokinetic properties

None stated

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber that are additional to those included in other sections.

6. Pharmaceutical particulars

6.1 List of excipients

Sr. No.	Name of Ingredient	Specification
1	Sucralose	USP
2	Sorbitol 70%	BP
3	Glycerin	BP
4	Methyl paraben	BP

5	Propyl paraben	BP
6	Di sodium EDTA	BP
7	Colour erythrosine supra	IHS
8	Flavour peppermint	IHS
9	Menthol	BP
10	Bronopol	BP
11	Colloidal Silicon dioxide	BP
12	Sodium citrate	BP
13	Sodium Benzoate	BP

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30℃. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container

Primary Packing: 200 ml clear glass bottle

Secondary Packing: Such 01 bottle is packed in a printed carton along with package insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

GBGL Pharma Limited