SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

BG ACID GEL 830/180/50

2. Qualitative and quantitative composition

Each 10 ml of BG ACID GEL contains:

Dried aluminium hydroxide gel USP 830 mg
Magnesium Hydroxide USP 180 mg
Simethicone USP 50 mg
Colour: Erythrosine
Flavoured sugar free base.

Excipients with known effects

Sorbitol 800mg/10ml

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Gel (Oral use)

Pink colour suspension with vanilla flavor

4. Clinical particulars

4.1 Therapeutic indications

BGACID gel is indicated as an antacid in case of ulcer and non-ulcer dyspepsia, flatulence and GERD. It provides fast relief from acidity symptoms such as indigestion, heartburn, sour and upset stomach.

4.2 Posology and method of administration

For oral administration:

Adults

5 -10ml taken 20 minutes to 1 hour after meals and at bedtime or as required up to a maximum of 3-4 times in a day

Children between 12-18 years

2.5 to 5 ml 3-4 times a day

Children aged 5-12 years

Maximum of 2.5 ml 3-4 times in a day

Children less than 5 years old

Do not give more than 2.5 ml three times in a day.

Elderly

The normal adult dose is appropriate.

4.3 Contraindications

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

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. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- This product contains methyl paraben and propyl paraben; these may cause allergic reactions (possibly delayed).

Paediatric population

In young children the use of magnesium hydroxide can produce a hypermagnesemia, especially if they present renal impairment or dehydration.

4.5 Interaction with other medicinal products and other forms of interaction

BG ACID GEL 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 drugs notably H_2 antagonists, atenolol, bisphosphonates, cefdinir, cefpodoxime, chloroquine, chlorpromazine, ciprofloxacin, cyclines, dasatinib monohydrate,

dexamethasone, diflunisal, digoxin, eltrombopag olamine, elvitegravir, ethambutol, fluoroquinolones, glucocorticoids, hydroxychloroquine, indomethacin, iron salts, isoniazid, ketoconazole, levothyroxine, lincosamides, metoprolol, nilotinib, phenothiazine neuroleptics, penicillamine, propranolol, raltegravir potassium, rifampicin, rilpivirine, riociguat, rosuvastatin, sodium fluorure, antiviral treatment combination of tenofovir alafenamide fumarate/emtricitabine/bictegravir sodium, tetracyclines, and vitamins.

With the integrase inhibitors (dolutegravir, raltegravir, bictegravir) the combination should be avoided (please refer to their SmPC for dose recommendations).

As a precaution, staggering the administration times of any orally administered drug and the antacid by at least 2 hours (4 hours for the fluoroquinolones).

Levothyroxine may also bind to simethicone 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).
Quinidine:

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

Tetracycline:

Because of the aluminium content, Maalox Plus should not be concomitantly administered with tetracycline-containing antibiotics or any tetracycline salts.

Citrates:

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

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

4.6 Pregnancy and lactation

The safety of BG ACID GEL (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.
Simethicone is not absorbed from the gastrointestinal tract.
No effect 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.

4.7 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 (see Section 4.4).

Frequency not known: Abdominal pain

Injury, poisoning and procedural complications:

Frequency not known:

Hyperaluminemia (related to Aluminium component).

Metabolism and nutrition disorders

Very rare: Hypermagnesemia, 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, osteomalacia (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via*: Pharmacy and Poisons Board*

Pharmacovigilance Electronic Reporting System (PvERS);

https://pv.pharmacyboardkenya.org

4.9 Overdose

Serious symptoms are unlikely following overdosage.

Reported symptoms of acute overdose with aluminium hydroxide and magnesium salts combination include diarrhoea, abdominal pain, vomiting.

Large doses of this product may trigger or aggravate intestinal obstruction and ileus in patients at risk (see section 4.4)

Aluminium and magnesium are eliminated through urinary route; treatment of acute overdose consists of administration of IV Calcium Gluconate, rehydration and forced diuresis. In case of renal function deficiency, haemodialysis or peritoneal dialysis is necessary.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for acid related disorders; Antacids with antiflatulents.

API	ATC Codes	Therapeutic group
Dried aluminium hydroxide	A02AB01	Antacid
Magnesium Hydroxide	A02AA04	Antacid
Simethicone	A03AX13	Antifoaming agent/anti-flatulent

BG ACID GEL is a balanced mixture of two antacids and an anti-flatulent/antifoaming agent simethicone. 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.

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 may decrease gastric

emptying, absorbed aluminium is eliminated in the urine, the aluminium compounds remaining in the gastrointestinal tract, which account for most of a dose, form insoluble, poorly absorbed aluminium salts in the intestines including hydroxides, carbonates, phosphates and fatty acid derivatives, which are excreted in the faeces. Magnesium hydroxide, given orally, 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.

5.3 Preclinical safety data

There are no pre-clinical data of relevance available

6. Pharmaceutical particulars

6.1 List of Excipients

SR.NO	**List of excipients**
1	Sodium Propyl Paraben
2	Sorbitol 70% solution
3	Sodium CMC
4	Xanthan gum
5	Saccharin Sodium
6	Sodium Citrate
7	Bronopol
8	Mentha Oil
9	Vanillin Powder
10	Menthol
11	Chloroform
12	Colour Erythrosine

Not applicable

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Store in a dry place, below 30°C.

Do not refrigerate or freeze

6.4 Special Precautions for storage

200 ml HDPE bottle and 15 ml measuring cup packed in a carton along with a pack insert.

6.5 Nature and content of container

200 ml HDPE bottle and 15 ml measuring cup packed in a carton along with a pack insert.

6.5 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorisation holder

Bliss GVS Pharma Ltd.

Reg. office: 102, Hyde Park, Saki Vihar Road, Andheri (E) Mumbai-400072.India

8. Marketing Authorization Number

CTD9878

9. Date of authorization /renewal of the authorization

12/09/2023

10. Date of revision of the text

07/05/2025