EDGE ANTACID SUSPENSION

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINAL PRODUCT

EDGE ANTACID SUSPENSION

Magnesium Trisilicate BP	250mg,
Light Magnesium Carbonate BP	250mg,
Sodium Bicarbonate BP	250mg
Aluminium Magnesium silicate BP	30mg

Dosage form:

Oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Magnesium Trisilicate BP	250mg,
Light Magnesium Carbonate BP	250mg,
Sodium Bicarbonate BP	250mg
Aluminium Magnesium silicate BP	30mg
Purified water	Q.S
Excipients	Q.S.

Flavour: Mint

3. PHARMACEUTICAL FORM

Oral suspension
White coloured, homogenous after shaking, mint flavoured suspension

4. Clinical particulars

4.1 Therapeutic indications

Edge antacid suspension is effective for the relief of:

- Heartburn
- dyspepsia
- Flatulence

4.2 Posology and method of administration

Posology

Adult: 2 – 4 teaspoonful 3-4 times daily and at bedtimes or as required
Children (6-12 years): 1 – 2 teaspoonful 3-4 times daily

Method of administration

Liquid Oral
Shake well before use

4.3 Contraindications

Edge antacid suspension is contraindicated for patients hypersensitive to any of the active substances or excipients, also patients with severe kidney failure or hypophosphotaemia.

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 encephalopathy, dementia, microcytic anemiaor worsen dialysis-induced osteomalacia. Aluminium hydroxide may be unsafe in patients with porphyria undergoing hemodialysis. The prolonged use of antacids in patients with renal failure should be avoided.

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

Edge antacid suspension 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 such as tetracyclines, vitamins, ciprofloxacin, ketoconazole, hydroxychloroquine, chloroquine,

chlorpromazine, rifampicin, cefdinir, cefpodoxime, levothyroxine, rosuvastatin, H2 antagonists, atenolol, cyclines, diflunisal, digoxin, bisphosphonates, ethambutol, fluoroquinolones, sodium fluoride, glucocorticoids, indomethacin, isoniazid, lincosamides, metoprolol, phenothiazine neuroleptics, penicillamine,propranolol and iron salts. 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).

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, it 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

4.6 Pregnancy and Lactation

The safety of Edge antacid suspension in pregnancy has not been established.

Pregnancy:

There are no available data on Edge antacid suspension use in pregnant women. No conclusions can be drawn regarding whether or not Edge antacid suspension is safe for use during pregnancy.

This drug should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the feotus.

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. No effect on the breastfed newborn/infant are anticipated since the systemic exposure of the breast feeding woman to aluminium hydroxide, magnesium hydroxide is negligible.

Effects on ability to drive and use machines

None specified

4.7 Undesirable effects

The following CIOMS frequency rating is used, when applicable:

Immune system disorders

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: Hypermagnesemia, including observations after prolonged administration of magnesium hydroxide to patients with renal impairmen

4.8 Overdose

Serious symptoms are unlikely following overdose.

Discontinue medication and correct fluid deficiency if necessary.

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.

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 Pharmacodynamics properties

EDGE antacid suspension is a balanced mixture of two antacids. 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

Pharmacokinetic properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients:

- Sorbitol solution 70% BP
- Methyl paraben BP
- Propyl paraben BP
- Bronopol BP
- Sodium Carboxyl methyl cellulose BP
- Guar gum BP
- Sodium Citrate BP
- Peppermint oil IHS
- Menthol BP

6.2 Incompatibilities

None

6.3 Shelf life

3 years (36months)

6.4 Special precautions for storage

Store in a cool, dry place below 30℃.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Primary pack: 200ml amber colored BRUT bottle with a customized **'Biopharma'** metallic cap

Equipment for administration: Transparent 10ml measuring cup

Secondary pack: customized 300gm outer pack

Shipping cartons

6.6 Special precautions for disposal <and other handling>

None

7. <APPLICANT/MANUFACTURER>

BIOPHARMA Nigeria limited
18, Sakajojo street, Odogunyan, Ikorodu
Lagos.
Email: info@biopharma.ng
Website: www.biopharma.ng
Phone number: 08060233328