SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

DR. MEYER'S GELACID SUSPENSION

1. **Name of the medicinal product**

Dr. Meyer's Gelacid Suspension

2. Qualitative and quantitative composition per 5ml:

Magnesium Hydroxide BP 150mg, Magnesium Trisilicate BP 50mg, Calcium Carbonate BP 500mg, Simethicone USP 5mg/5ml

For a full list of excipients, see section 6.1

3. Pharmaceutical form

Oral suspension

White suspension, homogenous after shaking, with the odour and taste of lemon.

4. Clinical particulars

4.1 Therapeutic indications

The symptomatic relief of:

a. Dyspepsia.

b. Heartburn.

c. Flatulence.

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.

Children

As an appropriate proportion of the adult dose.

Children under 5 years

Maximum of 5ml to be taken three times daily

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, 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 encephalopathy, dementia, microcytic anemia or 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

Dr. Meyer's Gelacid 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 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 simeticone which may delay or reduce the absorption of levothyroxine.

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, Gelacid Suspension 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 Fertility, pregnancy and lactation

The safety of Dr. Meyer's Gelacid Suspension in pregnancy has not been established.

Pregnancy:

There are no available data on Dr. Meyer's Gelacid Suspension use in pregnant women. No conclusions can be drawn regarding whether or not Dr. Meyer's Gelacid Suspension is safe for use during pregnancy. Dr. Meyer's Gelacid Suspension 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.

Simeticone 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 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 (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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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, ATC Code: A02AF02

Magnesium Trisilicate	- antacid
Magnesium Hydroxide	- antacid
Calcium Carbonate	- antacid
Simeticone	- antifoaming agent/antiflatulent

Gelacid Suspension 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.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

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

6. Pharmaceutical particulars

6.1 List of excipients

Microcrystalline cellulose and carmellose sodium

Hydroxpropylcellulose

Hydrogen peroxide 30%

Citric acid monohydrate

Sucrose

Sorbitol liquid 70% (non-crystallising) (E420)

Methylcellulose

Lemon flavour

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Unopened: 2 years

After opening: 6 months

6.4 Special precautions for storage

Store below 30° C.

Do not refrigerate or freeze.

6.5 Nature and contents of container

100ml and 200ml amber pet bottle with metallic screw cap

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorisation holder / Manufacturer

Farmex Meyer Limited
Km. 38, Lagos–Abeokuta Express Road,
Sango-Otta, Ogun State,
Nigeria.