



**SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC) TEMPLATE**

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

DR. MEYER'S GRIPE WATER

1. NAME OF THE MEDICINAL PRODUCT

DR. MEYER'S GRIPE WATER (Dill Oil 0.005ml, Fennel Oil 0.0007ml, Sodium Bicarbonate 50mg /5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Dill Oil	0.005ml
Fennel Oil	0.0007ml
Sodium Bicarbonate	50.00mg

Excipients:

Methyl-4-Hydroxybenzoate	10mg
Propyl-4-Hydroxybenzoate	1mg
Sucrose	2000mg
Chloroform	0.0025ml
Clare-Cel	5mg
Purified Water	to 5ml

For Full list of excipients refer section 6.1

3. PHARMACOLOGICAL FORM

Solution

Clear colourless liquid presented in 100ml & 200ml pet bottle with metallic screw cap packed in a carton

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dr. Meyer's Gripe water relieves acidity in infants and children.

4.2 Posology and Method of administration

Give 3 to 4 times a day between meals and at bedtime as required.

New-born infants: A half medicine measure (2.5 ml)

1 – 6 months: One medicine measure (5 ml)

Over 6 months – 2 years: Two medicine measures (10 ml)

Over 2 years: Two to three medicine measures (10 – 15 ml)

If you missed a dose, do not double the dose. Skip the missed dose and continue with the next dose as directed

Method of administration

Oral

4.3 Contraindications

Dr. Meyer's Gripe Water is contraindicated in:

- patients who are hypersensitive to sodium bicarbonate or to any of the excipients listed in section 6.1.
- patients with metabolic or respiratory alkalosis, hypocalcaemia or hypochlorhydria

4.4 Special Warnings and Precautions for Use

Dr. Meyer's Gripe Water should be given extremely cautiously to patients with heart failure, oedema, renal impairment, hypertension or aldosteronism.

Special care must be taken when administering **Dr. Meyer's Gripe Water** with other medicines, and in particular with salicylates, tetracyclines, barbiturates and lithium. (Refer to section 4.5).

Dr. Meyer's Gripe Water contains sucrose which may have an effect on the glycaemic

control of patients with diabetes mellitus.

4.5 Interactions with other medications

Bicarbonate may reduce or increase the rate and/or extent of absorption of a number of medicines due to raising intra-gastric pH. Alkalinisation of the urine leads to increased renal clearance of acidic medicines such as salicylates, tetracyclines and barbiturates. Conversely it may prolong the half-life of certain medicines and result in toxicity.

Sodium bicarbonate enhances the excretion of lithium. (Refer to section 4.4).

4.6 Pregnancy and lactation

Not applicable. **Dr. Meyer's Gripe Water** is not intended for administration to women of child-bearing age.

4.7 Effects on ability to drive and use machines

Not applicable. **Dr. Meyer's Gripe Water** is only intended for use in infants and children

4.8 Undesirable effects

The following side effects may occur:

Gastrointestinal disorders

Frequency unknown: Stomach cramps, belching, flatulence.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Excessive use of bicarbonate may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function. Symptoms include mood

changes, tiredness, slow breathing, muscle weakness, and irregular heartbeat. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients.

Treatment of metabolic alkalosis associated with bicarbonate overdose consists mainly of appropriate correction of fluid and electrolyte balance.

Replacement of calcium, chloride and potassium ions may be of particular importance. Excessive doses of sodium salts may also lead to sodium overloading and hyperosmolality (hypernatraemia). Symptoms of hypernatraemia include thirst, reduced salivation, lachrymation, fever, sweating, tachycardia, hypertension or hypotension, headache, dizziness, restlessness, irritability, weakness, muscular twitching and rigidity, somnolence, confusion, convulsions, coma, respiratory failure, and death.

Treatment for mild sodium excess includes drinking water and restricting sodium intake

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids with Sodium bicarbonate, ATC code: A02AH
Sodium bicarbonate is an antacid that neutralises acid secretions in the gastrointestinal tract.

5.2. Pharmacokinetic properties

Sodium bicarbonate neutralises gastric acid secretions with the production of carbon dioxide. Bicarbonate not involved in neutralising gastric acid is absorbed and in the absence of a deficit of bicarbonate in the plasma, the bicarbonate ions are then excreted in the urine rendering it alkaline, and there is an accompanying diuresis.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical Particulars

6.1 List of Excipients

Methyl-4-Hydroxybenzoate	10mg
Propyl-4-Hydroxybenzoate	1mg
Sucrose	2000mg

Chloroform		0.0025ml
Clare-Cel		5mg
Purified Water	to	5ml

6.2 Incompatibilities

None specific

6.3 Shelf-Life

36 Months

6.4 Special Precautions for Storage

Store below 30° C. Replace cap securely.

6.5 Nature and Contents of Container

100 ml and 200ml in transparent pet bottles with metallic screw cap / measuring cup packed in a carton.

6.6 Instructions for Handling

None specific.

7. Applicant / Manufacturer:

Farmex Meyer Limited

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