SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Moms Magic syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains:

Sodium Bicarbonate B.P ……1.2%
Sodium Citrate B.P……...0.5%
Anise Oil B.P …… …… 0.12%
Dill Oil B.P ……0.058%

Excipients: See section 6.1 for a full list of excipients.

3. PHARMACEUTICAL FORM

Syrup for oral administration.

A clear to slightly opalescent, pale yellow to amber-coloured liquid with a characteristic aromatic odour and sweet taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

This combination syrup is indicated for the symptomatic relief of:

- Hyperacidity, heartburn, and acid indigestion.
- Flatulence, abdominal distension, and bloating.
- Dyspepsia and gastric discomfort associated with excessive gas formation.
- Infantile colic and gripe (as an adjunctive carminative therapy).
- Nausea and eructation associated with gastric hyperacidity.

4.2 Posology and Method of Administration

Route of administration: Oral.

Shake well before use. Use the measuring cup or spoon provided.

Adults and children over 12 years of age:

> 10–15 ml (2–3 teaspoonfuls) three to four times daily, after meals and at bedtime, or as directed by a physician.

Children 6–12 years of age:

5–10 ml (1–2 teaspoonfuls) three times daily, after meals, or as directed by a physician.

Children 2–6 years of age:

2.5–5 ml (½–1 teaspoonful) three times daily, after meals, or as directed by a physician.

Infants 1 month–2 years of age:

2.5 ml (½ teaspoonful) three times daily, or as directed by a physician. May be mixed with a small amount of water, milk, or feed.

Neonates (under 1 month):

Not recommended unless specifically prescribed by a physician.

Special populations:

Older people: No special dosage adjustments required. Use with caution in patients with renal impairment, hypertension, or cardiac failure due to sodium content.

Renal impairment: Use with caution. Monitor serum electrolytes with prolonged use.

Hepatic impairment: No dosage adjustment required.

4.3 Contraindications

- Hypersensitivity to sodium bicarbonate, sodium citrate, anise oil, dill oil, or any of the excipients.
- Patients on sodium-restricted diets (e.g., severe hypertension, congestive cardiac failure, renal impairment, oedema).
- Severe renal impairment or anuria.
- Metabolic or respiratory alkalosis.
- Hypocalcaemia (risk of tetany with alkalosis).
- Hypernatraemia.
- Conditions associated with low urinary output unless under medical supervision.
- Patients receiving aluminium-based antacids concurrently.
- Appendicitis or undiagnosed abdominal pain (symptomatic relief may mask underlying pathology).

4.4 Special Warnings and Precautions for Use

- This product contains sodium. Each 5 ml contains approximately [X] mg of sodium. To be taken into consideration by patients on a controlled sodium diet.
- Prolonged or excessive use may cause systemic alkalosis (metabolic alkalosis), particularly in patients with renal impairment or in the elderly.

- Use with caution in patients with impaired renal function, cardiac disease, hypertension, peripheral and pulmonary oedema, or toxemia of pregnancy.
- Monitor serum electrolytes (sodium, potassium, calcium, bicarbonate) if used for more than 2 weeks or in patients with renal disease.
- May mask the symptoms of peptic ulcer or gastric malignancy. Do not use for more than 2 weeks without medical evaluation.
- Do not administer concurrently with aluminium-based antacids as citrate may increase aluminium absorption.
- Caution in patients with a history of kidney stones (urinary alkalinization may promote calcium phosphate or struvite stone formation).
- Essential oils (anise and dill) may cause allergic reactions in sensitive individuals, including contact dermatitis and respiratory symptoms.
- Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency should use with caution due to potential oxidative stress from essential oils.
- Diabetic patients should be aware that the syrup contains sucrose or other sugars (see section 6.1).
- This medicine should not be used as a long-term treatment for chronic dyspepsia without investigation of the underlying cause.

4.5 Interaction with Other Medicinal Products

- Aluminium-containing antacids: Concurrent use may increase aluminium absorption. Avoid concurrent administration.
- Acid-labile drugs (e.g., ketoconazole, itraconazole, atazanavir, rilpivirine): Antacids may reduce absorption. Administer at least 2 hours apart.
- Iron salts, tetracyclines, fluoroquinolones: Alkalinization reduces absorption. Administer at least 2 hours before or 4–6 hours after this product.
- Salicylates: Urinary alkalinization increases renal excretion of salicylates, potentially reducing therapeutic effect.
- Lithium: Sodium intake may reduce lithium reabsorption, decreasing serum lithium levels.
- Amphetamines, quinidine, ephedrine: Alkalinization of urine reduces renal excretion, potentially increasing toxicity.
- Methotrexate: Urinary alkalinization may alter methotrexate excretion.
- Corticosteroids: May increase risk of sodium retention and hypokalaemia when used concurrently.
- Diuretics (thiazides, loop diuretics): May exacerbate electrolyte disturbances (hypokalaemia, metabolic alkalosis).
- ACE inhibitors, ARBs, potassium-sparing diuretics: Increased risk of hyperkalaemia with potassium-containing formulations.

- Warfarin: Large doses of antacids may affect absorption of vitamin K-dependent factors.
- Levodopa: Antacids may increase levodopa absorption, potentially causing toxicity.

4.6 Fertility, Pregnancy and Lactation

Pregnancy:

There are limited data on the use of this combination in pregnant women. Sodium bicarbonate and sodium citrate have been used during pregnancy for many years without apparent harmful effects when used at recommended doses. However, use should be cautious, especially in the third trimester, due to sodium load and risk of fluid retention. Essential oils (anise and dill) should be used in moderation during pregnancy. Use only if the potential benefit justifies the potential risk to the fetus.

Lactation:

It is not known whether anise oil or dill oil are excreted in human milk. Sodium bicarbonate and sodium citrate are excreted in breast milk but are unlikely to cause harm at recommended doses. Caution should be exercised when administering to nursing mothers. Avoid excessive use.

Fertility:

No data available on effects on fertility.

4.7 Effects on Ability to Drive and Use Machines

No known effects on ability to drive and use machines. However, patients should be advised that if they experience dizziness or drowsiness (rare), they should avoid operating machinery or driving.

4.8 Undesirable Effects

Adverse reactions are listed by MedDRA System Organ Class and frequency category:

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).

System Organ Class	Adverse Reaction	Frequency
Metabolism and nutrition disorders	Metabolic alkalosis, hypernatraemia, fluid retention, hypokalaemia	Rare
Nervous system disorders	Headache, dizziness, tremor, irritability	Not known
Gastrointestinal disorders	Nausea, vomiting, abdominal cramps,	Common to Uncommon

	diarrhoea, constipation, rebound hyperacidity (with prolonged use), flatulence, eructation	
Renal and urinary disorders	Crystalluria, renal calculi (with prolonged use), increased urinary frequency	Rare
Skin and subcutaneous tissue disorders	Rash, pruritus, urticaria, allergic dermatitis (to essential oils)	Rare
Respiratory disorders	Cough, bronchospasm, respiratory irritation (to essential oils in sensitive individuals)	Very rare
General disorders	Thirst, weakness, oedema, fever	Uncommon

Observed post-marketing.

Reporting of suspected adverse reactions If you experience any side effects, talk to your doctor or pharmacist. By reporting side effects, you can help provide more information on the safety of this product. Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Symptoms of overdose may include:

- Metabolic alkalosis (muscle weakness, tremor, irritability, confusion, tetany)
- Hypernatraemia (thirst, oedema, headache, confusion, seizures)
- Hypokalaemia (muscle weakness, cardiac arrhythmias)
- Gastrointestinal disturbances (nausea, vomiting, abdominal pain, diarrhoea)

Management: Discontinue use. Supportive treatment should be initiated as appropriate. Rehydration with appropriate electrolyte replacement may be required. Monitor serum electrolytes, renal function, and acid-base status. Severe cases may require intravenous fluids and correction of electrolyte imbalances.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Antacids with antiflatulents and carminatives

ATC code: A02AH

Mechanism of action:

Sodium Bicarbonate: A rapid-acting, systemic antacid that neutralizes gastric hydrochloric acid to form sodium chloride, water, and carbon dioxide. It increases gastric pH promptly, providing symptomatic relief from heartburn and acid indigestion. It is readily absorbed systemically.

Sodium Citrate: An alkalinizing agent that, when metabolised, produces sodium bicarbonate, thereby exerting a prolonged buffering effect. It helps maintain an alkaline urinary pH and provides sustained neutralization of gastric acid. It also acts as an osmotic laxative at higher doses.

Anise Oil: Derived from Pimpinella anisum, anise oil contains anethole which has carminative, spasmolytic, and mild expectorant properties. It reduces lower oesophageal sphincter pressure, facilitates expulsion of gas from the gastrointestinal tract, and relieves flatulence and colic.

Dill Oil: Derived from Anethum graveolens, dill oil contains carvone and limonene which exert carminative and antispasmodic effects on the gastrointestinal smooth muscle. It reduces intestinal spasms, promotes expulsion of intestinal gas, and relieves abdominal distension and colic.

The combination provides rapid and sustained relief from gastric hyperacidity while the essential oils relieve associated flatulence, bloating, and spasmodic discomfort.

5.2 Pharmacokinetic Properties

Absorption:

Sodium bicarbonate is rapidly absorbed from the gastrointestinal tract. Sodium citrate is also well absorbed and metabolised to sodium bicarbonate. Anise oil and dill oil are partially absorbed from the GI tract; unabsorbed fractions are excreted in faeces.

Distribution:

Sodium bicarbonate distributes throughout extracellular fluid. Essential oils distribute to tissues and may cross the placenta.

Metabolism:

Sodium bicarbonate is not metabolised. Sodium citrate is metabolised in the liver to sodium bicarbonate and carbon dioxide. Anethole (from anise oil) is metabolised in the liver via oxidation and conjugation. Carvone and limonene (from dill oil) undergo hepatic metabolism.

Elimination:

Sodium and bicarbonate are excreted primarily by the kidneys. Carbon dioxide is exhaled via the lungs. Essential oil metabolites are excreted in urine and faeces.

5.3 Preclinical Safety Data

No preclinical safety data are available for the specific combination of sodium bicarbonate, sodium citrate, anise oil, and dill oil.

Sodium bicarbonate and sodium citrate have well-established safety profiles. Anise oil and dill oil have been used traditionally for many years with no significant safety concerns at the concentrations present in this formulation.

Reproductive toxicity: No reproductive toxicity studies have been performed with this combination. Anethole has shown weak oestrogenic activity in vitro; clinical relevance is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sucrose
- Liquid glucose
- Glycerol
- Propylene glycol
- Sodium benzoate (E211)
- Citric acid monohydrate
- Purified water
- Colouring agent (e.g., Caramel E150d)
- Flavouring agent

6.2 Incompatibilities

Incompatible with acidic drugs and acid-labile formulations.
Incompatible with aluminium-containing antacids (increases aluminium absorption).
Incompatible with iron salts, tetracyclines, and fluoroquinolones (reduces absorption).
Incompatible with oxidising agents.
Do not mix with other oral medicinal products unless specifically directed by a physician.

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

- Store below 30°C.
- Protect from light.
- Do not freeze.

- Keep the bottle tightly closed.
- Keep out of reach of children.

6.5 Nature and Contents of Container

Amber glass bottle with polypropylene child-resistant cap, or high-density polyethylene (HDPE) bottle with tamper-evident closure.

Pack sizes: 60ml & 100 ml,

6.6 Special Precautions for Disposal and Other Handling

- Any unused product or waste material should be disposed of in accordance with local requirements for pharmaceutical waste.
- Do not dispose of via wastewater or household waste.
- Use the measuring device provided to ensure accurate dosing.
- Do not use if the bottle or seal is damaged.

7. MARKETING AUTHORISATION HOLDER

Zain Pharma Pvt Limited Colchester Park, Go-Down No. 1, 2, and 3, off Mombasa Road (behind the Nice & Lovely house) Nairobi, Kenya

8. MARKETING AUTHORISATION NUMBER

CTD9466

9. DATE OF FIRST AUTHORISATION/RENEWAL

July 17 2025

10. DATE OF REVISION OF THE TEXT

July 17 2025