National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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1. Name of the Medicinal Product

MARLEYCID TABLETS

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2. Qualitative and Quantitative Composition

Each tablet contains:

- **Carbonate BP**: 3.9 mg
- **Sodium Carbonate BP**: 15.6 mg
- **Calcium Carbonate Heavy**: 220 mg
- **Magnesium Carbonate BP**: 220 mg

Excipients with known effect:

- Sodium: Approximately **12.5 mg** per tablet.
- Sorbitol: May cause a laxative effect in high doses.

For the full list of excipients, see section 6.1.

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3. Pharmaceutical Form

Tablet.

- Appearance: White to off-white, round, flat-faced tablets with beveled edges and a smooth surface.

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4. Clinical Particulars

4.1 Therapeutic Indications

- Treatment of symptoms associated with **gastric hyperacidity**, including:
  - Heartburn
  - Acid indigestion
  - Dyspepsia
- Alleviation of **bloating and flatulence**.
- Adjunctive therapy in conditions requiring reduced gastric acidity (e.g., peptic ulcers, gastroesophageal reflux disease [GERD]).

4.2 Posology and Method of Administration

Adults and adolescents (12 years and older):

- Chew 1–2 tablets thoroughly as needed when symptoms occur.
- Do not exceed 8 tablets in 24 hours.

Elderly:

- No specific dose adjustment required. Monitor closely for electrolyte imbalances or renal insufficiency.

Children (6–12 years):

- Chew 1 tablet as needed, up to a maximum of 4 tablets per 24 hours.
- Not recommended for children under 6 years without medical supervision.

Special Populations:

- **Renal impairment:** Use cautiously; monitor calcium and magnesium levels.
- **Hepatic impairment:** No specific dose adjustment needed.

Method of Administration:

- For oral use.
- Chew thoroughly before swallowing for optimal effect.

4.3 Contraindications

- Hypersensitivity to any active ingredients or excipients.
- **Hypercalcemia** or calcium-related disorders (e.g., hyperparathyroidism).
- **Severe renal insufficiency** or history of nephrolithiasis.
- **Hypophosphatemia** (risk of worsening deficiency).
- Sodium-restricted diets in conditions like severe hypertension, congestive heart failure, or pre-eclampsia.

4.4 Special Warnings and Precautions for Use

- **Renal insufficiency:** Risk of systemic magnesium accumulation, especially in prolonged use.
- **Sodium content:** Caution in patients on sodium-restricted diets or those with cardiovascular disease.
- **Prolonged use:** Avoid long-term continuous use to prevent rebound hyperacidity, metabolic alkalosis, or electrolyte imbalance.
- **Hypercalcemia risks:** Monitor patients with a history of kidney stones or those receiving high calcium intake from other sources.
- **Calcium-magnesium interactions:** Combined use may impair phosphate balance.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

- **Tetracyclines/fluoroquinolones:** Reduced bioavailability; separate administration by at least 4 hours.
- **Bisphosphonates:** Delayed absorption; take bisphosphonates at least 30 minutes before antacid.
- **Iron supplements:** Reduced iron absorption; administer antacids at least 2 hours after iron.
- **Cardiac glycosides:** Hypercalcemia may potentiate toxicity.
- **Levothyroxine:** Reduced efficacy; administer at least 4 hours apart.
- **Thiazide diuretics:** Increased risk of hypercalcemia.

4.6 Fertility, Pregnancy, and Lactation

- **Pregnancy:**
  - Safe in therapeutic doses. Avoid prolonged or excessive use to prevent milk-alkali syndrome or hypercalcemia.
- **Lactation:**
  - Safe for use as systemic absorption of active ingredients is minimal.
- **Fertility:**
  - No adverse effects reported.

4.7 Effects on Ability to Drive and Use Machines

- No effects on the ability to drive or operate machinery are expected.

4.8 Undesirable Effects

Common (>1/100):

- Constipation (from calcium carbonate).
- Diarrhea (from magnesium carbonate).

Uncommon (<1/1000):

- Nausea, belching, bloating.

Rare (<1/10,000):

- **Milk-alkali syndrome:** Characterized by hypercalcemia, alkalosis, and renal impairment.
- Allergic reactions (rash, itching, swelling, or anaphylaxis).

Post-marketing experience:

- Rare cases of electrolyte imbalance, including **hypermagnesemia** and **hypercalcemia**, in patients with renal dysfunction.

4.9 Overdose

Symptoms:

- Nausea, vomiting, abdominal discomfort, confusion, drowsiness, muscle weakness, arrhythmias (due to hypercalcemia or alkalosis).

Management:

- Discontinue product immediately.
- Hydrate with saline and monitor serum electrolytes.
- Severe hypercalcemia may require intravenous bisphosphonates or hemodialysis.

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5. Pharmacological Properties

5.1 Pharmacodynamic Properties

- **Pharmacotherapeutic group:** Antacids (ATC Code A02A2).
- **Mechanism of Action:** Neutralizes gastric acid, forming water, carbon dioxide, and soluble salts, reducing acidity and relieving symptoms.

5.2 Pharmacokinetic Properties

- Calcium carbonate and magnesium carbonate act locally in the stomach.
- Systemic absorption is minimal under normal conditions. Excess is excreted via feces or urine.

5.3 Preclinical Safety Data

- **Toxicology:** No evidence of mutagenicity, carcinogenicity, or teratogenicity in animal studies.
- **Reproductive studies:** No adverse effects on fertility or fetal development.

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6. Pharmaceutical Particulars

6.1 List of Excipients

- Microcrystalline cellulose
- Magnesium stearate
- Sorbitol
- Maize starch
- Purified talc

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months from the date of manufacture.

6.4 Special Precautions for Storage

- Store below 30°C.
- Protect from moisture and light.

6.5 Nature and Contents of Container

- Blister packs: 10, 20, or 30 tablets.
- HDPE bottles with child-resistant caps: 30, 60, or 100 tablets.

6.6 Special Precautions for Disposal

- Dispose of in accordance with local regulations.

8. Marketing Authorization Number(s)

MARLEY SHREE PHARMACEUTICAL NIG. LTD

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