SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Of

DE-SHALOM COMPOUND MAGNESIUM TRISILICATE TABLET

1. Name of the medicinal product

De-Shalom Compound Magnesium Trisilicate Tablet

2. Qualitative and quantitative composition

Each tablet contains: Magnesium Trisilicate BP 250mg

Calcium carbonate BP 200mg

For excipients see section 6.1

3. Pharmaceutical form

Chewable Tablet

4. Clinical particulars

4.1 Therapeutic indications

This antacid tablet is indicated for the relief of symptoms associated with excess stomach acid, including heartburn, indigestion, and dyspepesia.

4.2 Posology and method of administration

POSOLOGY

Chew 1-3 tablets three to four times daily, preferably after meals and at bedtime, or as directed by a healthcare professional.

Tablet should be chewed before swallowing

4.3 Contraindications

- Hypersensitivity to magnesium trisilicate, calcium carbonate, or any other ingredients in the formulation.
- Severe renal impairment or conditions that may lead to hypermagnesemia.

4.4 Special warnings and precautions for use

- Use with caution in patients with renal impairment, as accumulation of magnesium may occur.
- Prolonged use may lead to metabolic alkalosis.
- Patients should be advised to avoid taking other medications within 2 hours of this antacid to prevent interaction.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may alter the absorption of various medications, including but not limited to:

- ACE inhibitors
- Salicylates (e.g., aspirin)

- Antibiotics (e.g., tetracyclines, fluoroquinolones)
- Digoxin
- Levothyroxine
- Itraconazole and ketoconazole

It is recommended to allow at least 2 hours before or after taking other medications to minimize interaction risks

4.6 Pregnancy and lactation

Pregnancy

Limited data are available on the use of this antacid during pregnancy. It should only be used if clearly needed and prescribed by a healthcare provider.

Lactation

Calcium carbonate and magnesium trisilicate are generally considered safe during breastfeeding. However, it is advisable to consult a healthcare provider before use.

4.7 Effects on ability to drive and use machines

This medication is not expected to affect the ability to drive or operate machinery. However, if any side effects occur, caution should be exercised.

4.8 Undesirable Effects

Common side effects may include:

- Constipation
- Diarrhea
- Abdominal discomfort

Serious side effects are rare but may include symptoms of hypermagnesemia (e.g., muscle weakness, confusion). Patients should seek medical attention if they experience severe side effects.

4.9 Overdose

Symptoms:

Symptoms of overdose may include nausea, vomiting, diarrhea, and abdominal pain.

Management

In case of overdose, symptomatic treatment should be initiated. Patients should be monitored for signs of hypermagnesemia and metabolic alkalosis.

5. Pharmacological Properties

5.1Pharmacodynamic properties

Pharmacotherapeutic Group: Antacids

ATC Code: A02A

Mechanism of Action

Magnesium trisilicate and calcium carbonate neutralize gastric acid, providing symptomatic relief from

heartburn and indigestion.

Antacids provide rapid control of acidity by neutralizing the gastric acid. This action results in increased pH of stomach contents, thus providing the relief of the symptoms of the hyperacidity. Acid concentration within the lumen of oesophagus is also reduced, resulting in an increased intraoesophageal pH. Antacids also reduce pepsin activity

5.2 Pharmacokinetic properties

Calcium carbonate, given orally slowly reacts with the hydrochloric acid in the stomach to form Calcium chloride, some of which is absorbed. The presence of food or other factors that decrease gastric emptying prolongs the availability of calcium carbonate to react and may increase the amount of calcium chloride

formed. Absorbed calcium is eliminated in the urine and patients with renal failure are therefore at particular risk of accumulation.

Magnesium, given by mouth, reacts relatively rapidly with hydrochloric acid in the stomach to form magnesium chloride and water. Approximately 10% of the magnesium is slowly absorbed from the gastrointestinal tract and excreted in the urine; the rest is excreted via the faeces.

5.3 Preclinical safety data

Preclinical studies indicate that both magnesium trisilicate and calcium carbonate have a favorable safety profile when used as directed.

6. Pharmaceutical particulars

6.1 List of excipients

- Corn Starch
- Menthol Crystal
- Peppermint Oil
- Starch (paste)
- Starch (bulk)
- Sucrose
- Magnesium Stearate
- Talcum Powder
- Ethanol (96%)
- P.V.P
- Methyl paraben
- Propyl paraben
- Xanthan gum

6.2 Incompatibilities

None known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30°C.

Keep out of reach of children.

6.5 Nature and contents of container

500 tablets per HDPE container

6.6 Special precautions for disposal and other handling

No special requirements apart from NAFDAC guidelines

7. Marketing authorisation holder/ Manufacturer

DE-SHALOM PHARM LAB NIG. LTD.

Km 4, Iloko-Ijesa Road, Ilesa, Osun-State, Nigeria.

Phone:08034088756

Email: deshalompharm@gmail.com