Professional Information for Medicines for Human Use:

MAGASIL Mixture

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

MAGASIL Mixture

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL mixture contains:

Magnesium carbonate, light 500 mg

Magnesium trisilicate 500 mg

Sodium bicarbonate 500 mg

Preservative: Chloroform 0,17 % *v/v.*

Contains alcohol: Ethanol 1,45 % *v/v*

Sugar free.

Contains sweeteners:

Sodium cyclamate 36 mg per 10 mL

Sodium saccharin 4 mg per 10 mL

Sodium content: 141,4 mg/10 mL

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Mixture.

A white homogenous mixture with peppermint odour and taste.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of acid ingestion, heartburn, hyperacidity, dyspepsia, gastritis and reflux oesophagitis.

4.2 Posology and method of administration

Posology

General information

For use in adults only. Do not use the maximum dosage of this product for more than 2 (two) weeks, except under the advice and supervision of a medical practitioner or use as directed by a doctor.

Adults

Two to four medicine measures (i.e. 10 mL to 20 mL) every four hours.

Method of administration

MAGASIL mixture is for oral administration.

SHAKE THE BOTTLE BEFORE USE.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or any excipients listed in section 6.1.
- Severe renal failure.
- Hypophosphataemia.
- Patients who must control sodium intake e.g. congestive heart failure, hypertension, cirrhosis of the liver (see section 4.4).
- Patients with metabolic or respiratory alkalosis.
- Patients with hypocalcaemia.
- Patients with hypochlorhydria.

4.4 Special warnings and precautions for use

Fluid retention

MAGASIL should be used with caution in patients with fluid retention. In view of the sodium bicarbonate content, MAGASIL should also be administered extremely cautiously to patients with renal impairment, to patients receiving corticosteroids or patients with respiratory acidosis, eclampsia, or aldosteronism.

Hypermagnesaemia

Overdose, or excessive or prolonged intake of magnesium containing antacids, such as MAGASIL, may give rise to hypermagnesaemia, especially in patients with renal insufficiency (see sections 4.8 and 4.9).

Symptoms of hypermagnesaemia include nausea, vomiting, flushing of the skin, thirst, hypotension due to peripheral vasodilation, drowsiness, confusion, loss of tendon reflexes due to neuromuscular blockade, muscle weakness, CNS and respiratory depression, bradycardia, cardiac dysrhythmias, coma, and cardiac arrest.

Hypokalaemia and metabolic alkalosis

Excessive administration of sodium bicarbonate, as in MAGASIL may lead to hypokalaemia and metabolic alkalosis, especially in patients with impaired renal function (see sections 4.8 and 4.9). Symptoms of hypokalaemia and metabolic alkalosis may include mood changes, mental disturbances such as restlessness, tiredness, shortness of breath, muscle weakness, irregular heartbeat, convulsions and coma.

Sodium overload

Excessive doses of sodium salts, such as sodium bicarbonate as in MAGASIL may lead to sodium overloading and hyperosmolality. which may exacerbate hypertension, heart failure, peripheral or

pulmonary oedema, renal impairment, pre-eclampsia or other conditions associated with sodium retention (see section 4.3).

Muscular disorders

Muscle hypertonicity, twitching and tetany may develop especially in hypocalcaemic patients (see section 4.8).

Gastrointestinal disorders

Sodium bicarbonate, as in MAGASIL, can cause stomach cramps and flatulence because of excess carbon dioxide production. Magnesium salts as in MAGASIL may cause diarrhoea in some patients (see section 4.8).

Renal calculi

Long-term, excessive use has been associated with the development of silica-based renal calculi (see section 4.8).

Excipients

Sodium

MAGASIL contains 141,4 mg sodium per 10 mL dose, equivalent to 7,1 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

Alcohol (ethanol)

MAGASIL contains 0,116 mg of alcohol (ethanol) in each 10 mL. The amount of alcohol in 10 mL of this medicine is equivalent to 29 mL beer or 11,6 mL wine. The small amount of alcohol in MAGASIL will not have any noticeable effects on adults.

4.5 Interaction with other medicines and other forms of interaction

Concomitant use with other medicines

Antacids, such as MAGASIL, may interact with a number of other medicines by altering their absorption and, sometimes, their elimination, thereby reducing their effectiveness. Antacids may also damage enteric coatings designed to prevent dissolution in the stomach. In order to minimise the risk of interactions, MAGASIL should not be taken within two to four hours of other medicines (allow at least 4 hours before or 2 hours after erlotinib).

Examples of other medicines which may be affected include, but are not limited to ACE inhibitors, salicylates (e.g. aspirin), atazanavir, azithromycin, barbiturates, bile acids, bisphosphonates, cephalosporin antibiotics, fluoroquinolone antibiotics, chloroquine and hydroxychloroquine, deflazacort, digoxin, dipyridamole, eltrombopag, erlotinib, fexofenadine, gabapentin, iron preparations, isoniazid, itraconazole, ketoconazole, lansoprazole, levothyroxine, lithium, methenamine, mycophenolate, nitrofurantoin, penicillamine, phenothiazines, phenytoin, proguanil, rifampicin, rosuvastatin, sulpiride, tetracyclines, tipranavir, ulipristal (avoid use with antacids).

Polystyrene sulphonate

Concomitant use with polystyrene sulphonate has the potential risk of reduced effectiveness of the resin in binding potassium and of metabolic alkalosis and intestinal obstruction.

4.6 Fertility, pregnancy and lactation

The potential risk for humans is unknown. As there is no specific data for this product, it is recommended that MAGASIL mixture only be used in pregnancy on the advice of a doctor.

Caution should be exercised when prescribing to pregnant women as this product contains sodium (see section 4.4).

4.7 Effects on ability to drive and use machines

MAGASIL has no or negligible influence on the patient's ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

Diarrhoea, stomach cramps and flatulence may occur (see section 4.4).

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Frequency unknown	Hypermagnesaemia (see section 4.4), hypokalaemia (see section 4.4), metabolic alkalosis (see section 4.4),
Gastrointestinal disorders	Frequency unknown	Diarrhoea, stomach cramps, flatulence (see section 4.4)
Musculoskeletal and connective tissue disorders	Frequency unknown	Muscle hypertonicity, twitching, tetany (see section 4.4)
Renal and urinary disorders	Frequency unknown	Silica-based renal calculi (see section 4.4)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

4.9 Overdose

Symptoms and signs

Overdose, or excessive or prolonged intake of MAGASIL may give rise to hypermagnesaemia, hypokalaemia and metabolic alkalosis (see section 4.8). For description of symptoms and signs of these conditions, see section 4.4.

Treatment

Treatment of mild hypermagnesaemia is usually limited to restricting magnesium intake. In severe hypermagnesaemia, ventilatory and circulatory support may be required. Treatment should consist of the intravenous administration of calcium gluconate injection 10 % at a dose of 10 – 20 mL, to counteract respiratory depression or heart block. If renal function is normal, adequate fluids should be given to assist magnesium removal from the body. Haemodialysis may be necessary in patients with renal impairment or for whom other methods prove ineffective.

Metabolic alkalosis and hypernatraemia can be treated by appropriate correction of fluid and electrolyte balance. Replacement of calcium, chloride, and potassium ions may be of particular importance.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 11.4.1 Antacids - Acid neutralisers

ATC Code A02AA10 : Magnesium compounds, combinations

Mechanism of action

MAGASIL is a mixture containing magnesium carbonate, magnesium trisilicate and sodium bicarbonate. MAGASIL is an antacid with slow neutralising action on stomach acid and mild laxative action.

Magnesium carbonate acts as an antacid by reacting with hydrochloric acid in the stomach to form soluble magnesium chloride and carbon dioxide, thereby neutralising excess gastric acid and providing relief from heartburn and indigestion. It is commonly combined with other antacids for enhanced effect.

Magnesium trisilicate functions as an antacid with a relatively slow neutralising action. It reacts with gastric acid, increasing the pH of stomach contents. Additionally, it forms a gelatinous silicon dioxide that can coat and protect the gastrointestinal mucosa, offering further symptomatic relief and promoting healing of ulcerated surfaces.

Sodium bicarbonate provides rapid neutralisation of gastric acid by reacting with hydrochloric acid to produce sodium chloride, water, and carbon dioxide. This helps quickly alleviate symptoms of acid indigestion and heartburn.

5.2 Pharmacokinetic properties

Magnesium chloride and hydrated silica gel are formed during the neutralisation. About 5 % of magnesium is absorbed and traces of liberated silica may be absorbed and excreted in the urine.

Any sodium bicarbonate not neutralised in the stomach is absorbed and excreted as bicarbonate and sodium ions in the urine in the absence of a plasma deficit.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chloroform

Chloroform spirit

Peppermint flavour FLV6147ZA

Purified water

Sodium cyclamate

Sodium saccharin

Xanthan gum.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a cool, dark place at or below 25 ºC.

6.5 Nature and contents of container

100 mL, 200 mL and 500 mL amber PVC bottles with white LDPE snap-on caps and 2,5 L amber HDPE containers with white LDPE caps.

100 mL and 200 mL white HDPE bottles with white LDPE flip-top cap.

Foil sachets containing 10 mL packed in a printed outer carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Gulf Drug Company (Pty) Ltd

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8. REGISTRATION NUMBER

E1402 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

22 January 2026