PROFESSIONAL INFORMATION

Complementary Medicine

Discipline-Specific, Combination product

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

MĒLTEEZ™ INDIGESTION, powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1,20 g stick contains:

Calcium carbonate	650 mg
providing Calcium (elemental)	260 mg
Magnesium carbonate	75 mg
providing Magnesium (elemental)	22 mg
Deglycyrrhizinated liquorice (DGL) extract	8 mg
[*Glycyrrhiza uralensis* root, 50:1 extract providing 400 mg dried herb equivalent]	
Extract does not contain more than 1,5 % glycyrrhizin/ glycyrrhizic acid	

Contains Sugar.

Sucrose 421 mg per 1,20 g stick.

Contains Sweetener.

Stevia 20 mg per 1,20 g stick

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder

Light brown powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

MĒLTEEZ INDIGESTION is indicated for use in adults and children 12 years and older.
Contributes to the normal function of digestive enzymes and promotes gastrointestinal comfort.

4.2. Posology and method of administration

Posology

Adults and children aged 12 years and older: Contents of one stick are to be placed directly on the tongue and allowed to dissolve slowly in the mouth.
Maximum: Five sticks per day.

Doses of MĒLTEEZ INDIGESTION and other medications should be separated (see section 4.5).

Paediatric population

MĒLTEEZ INDIGESTION is contraindicated for use in children under 6 years of age.
MĒLTEEZ INDIGESTION is not indicated for use in children under 12 years of age.
The dosage for children aged 12 years and older is the same as for adults.

Method of administration

For oral use.

4.3. Contraindications

- Hypersensitivity to the active ingredients or to other plants of the Fabaceae family or to any of the excipients listed in section 6.1.
- Hypercalcaemia
- Hypercalciuria
- Hyperparathyroidism
- Hypophosphatemia
- Nephrolithiasis
- Severe renal insufficiency
- Zollinger-Ellison Syndrome
- Hypermagnesemia
- Alkalosis
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency
- Low phosphate diet

- Concomitant use of cardiac glycosides
- Children under 6 years of age

4.4. Special warnings and precautions for use

Care should be taken in:

- Pregnancy
- Lactation
- Renal impairment/ disease. Patients should be closely monitored.
- Hepatic impairment/ disease
- Diabetes mellitus
- Oedema
- Myasthenia gravis
- Other neuromuscular disease
- Cardiac conditions/disorders/disease
- Vascular disorders/disease, including hypertension
- Hypokalaemia
- Concomitant use with cardiac medications, corticosteroids, stimulant laxatives, or other health products that may contribute to electrolyte imbalance

The maximum daily dose should not be exceeded.

Consumers should consult a relevant healthcare provider if digestive discomfort persists or worsens.

Consumers should discontinue use and consult a relevant healthcare provider if they experience flushing, dizziness or syncope, muscle paralysis, or dyspnoea.

4.5. Interaction with other medicines and other forms of interaction

MĒLTEEZ INDIGESTION may interact with certain medicines.

Concurrent use of MĒLTEEZ INDIGESTION and the following medicines is contraindicated:

- Cardiac glycosides. Calcium can increase the effects of digoxin by pharmacodynamic synergism. DGL (Deglycyrrhizinated liquorice) might affect potassium levels and lead to an increased risk of digoxin toxicity.

Caution is advised when used concurrently with:

- Diuretics. Thiazide diuretics increase levels of calcium by decreasing renal clearance, which can lead to hypercalcemia. DGL might intensify the potassium-wasting effects of most diuretics and interfere with the effectiveness of potassium-sparing diuretics.
- Tetracyclines. Calcium can decrease the absorption and effect of tetracycline antibiotics. Magnesium can form insoluble complexes with tetracyclines and decrease the absorption thereof. MĒLTEEZ INDIGESTION should be taken 2 hours before or 4 hours after tetracyclines.
- Quinolone antibiotics. Magnesium can form insoluble complexes with quinolone antibiotics and decrease the absorption thereof. MĒLTEEZ INDIGESTION should be taken 2 hours before or 4-6 hours after quinolones.
- Bisphosphonates. Calcium decreases the levels of bisphosphonates by inhibition of GI absorption. Magnesium decreases the absorption of bisphosphonates. Doses should be separated by 2 hours.
- Calcium channel blockers. Either increases the toxicity or effect of the other by pharmacodynamic synergism. Calcium channel blockers may increase the toxic effects of magnesium; magnesium may increase the hypotensive effects of calcium channel blockers.
- Ketoconazole. Calcium can decrease the level or effect of ketoconazole by inhibition of GI absorption. Doses should be separated by 2 hours.
- Atazanavir. Calcium can decrease the level or effect of atazanavir by increasing gastric pH. Atazanavir solubility decreases as pH increases. Doses should be separated by 2 hours.
- Dolutegravir. Magnesium can decrease absorption and thus the level or effect of dolutegravir. Dolutegravir should be taken 2 hours before or 6 hours after taking MĒLTEEZ INDIGESTION.
- Gabapentin. Magnesium can decrease absorption and thus the level or effect of gabapentin. Doses should be separated by 2 hours.
- Levothyroxine. Magnesium can decrease the level and effect of levothyroxine. Doses should be separated by 4 hours.
- Fexofenadine. Magnesium may cause adsorption of fexofenadine in the gastrointestinal tract, leading to a decrease in the absorption of fexofenadine. Doses should be separated by 2 hours.
- Warfarin. DGL might decrease the effectiveness of warfarin, thereby increasing the risk of blood clotting.
- Antihypertensives. DGL might increase salt and water retention, leading to a decrease in the effectiveness of antihypertensives.
- Paclitaxel and cisplatin. DGL might decrease the effectiveness of these medicines.
- Corticosteroids. DGL might increase the adverse effects of corticosteroids.

- Estrogens. DGL might alter the effectiveness of estrogens.
- Oral contraceptives. DGL might alter the effectiveness of oral contraceptives.
- Stimulant laxatives. DGL might aggravate electrolyte imbalance.
- Other health products that may contribute to electrolyte imbalance. DGL might aggravate electrolyte imbalance.
- P450 substrates. DGL might affect the P450 enzymes (particularly CYP3A4).

4.6. Fertility, pregnancy and lactation

Pregnancy

Not established. In the absence of sufficient data, use during pregnancy is not recommended.

Breastfeeding

Not established. In the absence of sufficient data, use during pregnancy is not recommended.

Fertility

No fertility data available

4.7. Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.
MĒLTEEZ INDIGESTION contains ingredients with possible side effects that can affect the ability to drive and use machines.

4.8. Undesirable effects

a) Summary of the safety profile

Should an allergic reaction occur, use should be discontinued.

b) Tabulated summary of adverse reactions

Classification	Frequency	Side effects
Calcium carbonate		
Metabolism and nutrition disorders	Unknown	Hypophosphatemia (which can include muscle weakness, pain, paraesthesia, loss of appetite, fatigue, confusion, irritability, seizures)

		Hypercalcaemia (which can include muscle weakness, aches, cramps, fatigue, headaches, irritability, confusion, drowsiness, frequent urination, polydipsia, abdominal pain, decreased appetite) Alkalosis (which can include nausea, vomiting, confusion, light-headedness, hand tremors, numbness or tingling in the face, hands, or feet) Milk-alkali syndrome (which can include frequent urge to urinate; continuing headache; continuing loss of appetite; nausea or vomiting; unusual tiredness or weakness; hypercalcaemia, alkalosis and renal impairment)
Gastrointestinal disorders	Unknown	Constipation Flatulence Rebound acidity Nausea Vomiting
Magnesium carbonate		
Nervous system disorders	Unknown	Dizziness Syncope Muscle paralysis
Vascular disorders	Unknown	Flushing
Respiratory, thoracic and mediastinal disorders	Unknown	Dyspnoea
Gastrointestinal Disorders	Unknown	Diarrhoea
Deglycyrrhizinated liquorice (DGL)		

Immune system disorders	Unknown	Hypersensitivity reactions
Gastrointestinal disorders	Unknown	Flatulence Bloating Nausea Mild abdominal discomfort

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.

4.9. Overdose

In overdose, side effects can be precipitated and/or increased by severity (see section 4.8).

Symptoms of overdose of magnesium, especially in patients with impaired kidney function, may include drowsiness, bradycardia, dyspnoea, dizziness or fainting, blurred or double vision, and coma.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Complementary Medicine

D33.7 Discipline-Specific, Combination Product

5.2. Pharmacokinetic properties

The pharmacokinetic properties have not been established.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cool mint flavour

Sucrose

Debittered stevia

Silicon dioxide

6.2. Incompatibilities

Not applicable

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Store in the original packaging.

Protect from light and moisture.

6.5. Nature and contents of container

Sticks, filled with 1,20 g light brown powder, packed into an outer carton.

Pack size: 10

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. PROSPECTIVE HOLDER OF CERTIFICATE OF REGISTRATION

Talo Consumer Solutions (Pty) Ltd

30 Bell Crescent

Hennopspark Ext 7

Centurion

0172

8. REGISTRATION NUMBER

To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF THE REVISION OF TEXT

January 2026