

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

S0

1. NAME OF THE MEDICINE

MĒLTEEZ™ RELAX, powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1,35 g stick contains:

Magnesium citrate malate	320 mg
providing Magnesium (elemental)	45 mg
L-Theanine	250 mg
<i>Melissa officinalis</i> (Lemon Balm) [Leaf, 10:1 extract providing 1500 mg dried herb equivalent]	150 mg

Sugar Free.

Contains sugar alcohol: Xylitol 573,25 mg per 1,35 g stick.

Contains sweetener: Stevia powder 20,00 mg per 1,35 g stick.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder

Off-white/ light beige powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MĒLTEEZ RELAX is indicated for use in adults. It helps to support relaxation and contributes to a reduction of tiredness and fatigue.

4.2 Posology and method of administration

Posology

Adults: One stick daily.

Contents are to be placed directly on the tongue and allowed to dissolve slowly in the mouth. It can also be dissolved in a glass of water.

It is advised that other medications are not taken for at least two (2) hours before or six (6) hours after taking this product (see section 4.5)

Paediatric population

Not indicated for use in children or adolescents under the age of 18 years.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to the active ingredients or other plants of the *Lamiaceae* (mint) family or any of the excipients listed in section 6.1.
- Appendicitis or acute surgical abdomen
- Faecal impaction or rectal fissures
- Intestinal obstruction or perforation
- Gastric lesions and disorders.
- Myocardial damage
- Cardiovascular conduction disorders, e.g., heart block
- Low-sodium diet
- Existing electrolyte imbalance
- Acute dehydration.
- Not indicated for use in children or adolescents under the age of 18 years.

4.4 Special warnings and precautions

MĒLTEEZ RELAX should be used with care:

- In renal impairment.
- In myasthenia gravis or other neuromuscular diseases.
- In cardiac conditions. Magnesium may worsen cardiac conditions. Use is contraindicated in certain conditions (see section 4.3)
- In pregnancy and lactation. Use is not recommended (see section 4.6).
- May cause drowsiness. Must be used with caution when driving or operating machinery.
- A healthcare provider should be consulted if restlessness, tiredness, or fatigue persist or worsen.
- The indicated daily dose should not be exceeded.
- MĒLTEEZ RELAX may affect the bioavailability and effectiveness of other oral medicines when taken concomitantly (see section 4.5).

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

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed for MĒLTEEZ RELAX; however, some ingredients have the potential to interact with other medications or products.

Caution is advised when used concurrently:

- Bisphosphonates. Magnesium may decrease GI absorption of bisphosphonates.
- Tetracyclines. Magnesium may decrease the absorption of oral tetracycline.
- Quinolones. Magnesium may decrease the absorption of oral quinolone
- Gabapentin. Magnesium may decrease the absorption of oral gabapentin
- Calcium channel blockers. Calcium channel blockers may increase the toxic effects of magnesium; magnesium may increase the hypotensive effects of calcium channel blockers.
- Dolutegravir. Magnesium can interact with dolutegravir and reduce its effectiveness.
- Levothyroxine. Magnesium may decrease the absorption of oral levothyroxine.
- CNS depressants. L-Theanine may potentiate the effect.
- Antihypertensive medication. L-Theanine may potentiate the effect.
- Stimulants. L-Theanine may decrease effectiveness.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No fertility data available.

4.7 Effects on ability to drive and use machines

May cause drowsiness. Caution should be exercised when driving and using machines.

4.8 Undesirable effects

Classification	Frequency	Side effects
Magnesium		
Nervous system disorders	Unknown	Dizziness, syncope, muscle paralysis
Vascular disorders	Unknown	Flushing
Respiratory, thoracic and mediastinal disorders	Unknown	Dyspnoea
Metabolism or nutrition disorders	Unknown	Electrolyte imbalance
Gastrointestinal disorders	Unknown	Nausea, vomiting, abdominal pain/cramping, diarrhoea, flatulence
L-Theanine		
Psychiatric disorders	Unknown	Irritability
Nervous system disorders	Unknown	Headache, dizziness
Gastrointestinal disorders	Unknown	Abdominal pain, nausea, diarrhoea
<i>Melissa officinalis</i> (lemon balm)		
Nervous system disorders	Unknown	Drowsiness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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).

Gastrointestinal discomfort in mild cases may be treated by discontinuing MĒLTEEZ RELAX and increasing fluid intake.

Hypermagnesemia

Characterised by flushing, headache, thirst, hypotension, nausea, vomiting, confusion, reduced tendon reflexes due to neuromuscular blockade, muscle weakness, cardiac arrhythmias, and cardiac arrest.

Symptoms of overdose, especially in patients with impaired kidney function, may also include drowsiness, slow heartbeat, respiratory depression, dizziness or fainting, blurred or double vision, and coma.

Treatment: Use should be discontinued. The patient should consult a doctor or pharmacist or seek medical care.

In acute toxicity, intravenous calcium gluconate can be used to counteract the effects of magnesium.

In patients with renal failure or very severe toxicity, dialysis may be required.

Patients should be clinically monitored.

Supportive treatment includes ensuring adequate ventilation, circulation, treatment of hypotension, and encouraging good urine flow by giving adequate fluids orally or intravenously as appropriate.

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

Xylitol (sugar alcohol)

Flavouring (orange)

Stevia powder, debittered (sweetener)

Silicon dioxide

Citric acid anhydrous

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 the container

Sticks, filled with 1,35 g off-white/ light beige 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

To be allocated.

10. DATE OF REVISION OF TEXT

January 2026