PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE (HEALTH SUPPLEMENT)

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

NutriPure Magnesium Gummies (65 mg Magnesium, gummies)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gummy contains:

Trimagnesium citrate	580,36 mg
providing Magnesium (elemental)	65 mg

Contains sugar: Glucose syrup (1,25 g); Sucrose (0,94 g)

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gummies

NutriPure Magnesium Gummies is a conoid shaped, red gummy with a raspberry flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

NutriPure Magnesium Gummies is a health supplement containing magnesium that:

- Contributes to normal energy-yielding metabolism,
- Contributes to normal electrolyte balance,
- Contributes to a reduction of tiredness and fatigue,
- Contributes to the maintenance of normal muscle function,
- Contributes to normal protein synthesis.

4.2. Posology and method of administration

Posology

Adults: Take one gummy daily.

Method of administration

Take the chewable gummies orally.

Do not take on an empty stomach, best to be taken with a meal.

4.3. Contraindications

This product should not be used by patients who have an allergy or are hypersensitive to any of the ingredients.

If symptoms worsen, consult a relevant health care provider.

4.4. Special warnings and precautions for use

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take NutriPure Magnesium Gummies.

Contains glucose syrup & sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Do not exceed the stated recommended daily dose without consulting a relevant health care provider.

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding, as safety has not been established established for NutriPure Magnesium Gummies (see section **4.6. Fertility, pregnancy and lactation**).

4.5. Interactions with other medicines and other forms of interaction

Interaction with Medicines

AMINOGLYCOSIDE ANTIBIOTICS: Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.

KETAMINE: Magnesium might precipitate ketamine toxicity. Since both magnesium and ketamine block the NMDA receptor, magnesium is thought to have potentiated the effects of ketamine.

LEVODOPA/CARBIDOPA: Magnesium can reduce the bioavailability of levodopa/carbidopa. In vitro and animal research shows that magnesium produces an alkaline environment in the digestive tract, which might lead to degradation and reduced bioavailability of levodopa/carbidopa.

TETRACYCLINES: Magnesium decreases absorption of tetracyclines. Magnesium can form insoluble complexes with tetracyclines in the gut and decrease their absorption and antibacterial activity. Advise patients to take these medicines 1 hour before or 2 hours after magnesium supplements.

Interaction with Herbs and Supplements

CALCIUM: High doses of calcium can decrease dietary magnesium absorption. Advise patients at high risk for magnesium deficiency to take calcium supplements at bedtime, instead of with meals, to avoid inhibiting dietary magnesium absorption.

VITAMIN D: High doses of some forms of vitamin D can increase magnesium absorption. Various forms of vitamin D, including ergocalciferol, 25-hydroxyergocalciferol, calcifediol, and calcitriol increase magnesium absorption, especially when taken in high doses.

ZINC: High doses of zinc may decrease magnesium absorption.

Interactions with Foods

None known.

Interactions with Lab Tests

ALKALINE PHOSPHATASE: Magnesium salts can cause a false increase in serum alkaline phosphatase test results due to the activation of enzymes used in laboratory procedures.

CALCIUM: Magnesium salts can cause a false increase in serum calcium test results in some procedures using edetate disodium (EDTA).

4.6. Fertility, pregnancy and lactation

Safety in pregnancy and when breastfeeding has not been established, consult a health care provider prior to use (see section **4.4. Special warnings and precautions for use**).

The effect on fertility is unknown.

4.7. Effects on ability to drive and use machines

There is no known effect on the ability to drive and use machines.

4.8. Undesirable effects

The most frequent adverse effects include diarrhoea, gastrointestinal irritation, nausea, and vomiting.

If any adverse effects do occur, please discontinue use and consult your physician.

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 asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9. Overdose

There is insufficient reliable information available about the presentation or treatment of overdose.

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

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

D34.7 Minerals

Magnesium

- Contributes to normal energy -yielding metabolism,
- Contributes to normal electrolyte balance,
- Contributes to a reduction of tiredness and fatigue; Magnesium has been theorized to regulate sleep by reducing inflammation, oxidative stress and by activating N-methyl-D-aspartate and gamma-aminobutyric acid (GABA),
- Contributes to the maintenance of normal muscle function; Extracellular magnesium is critical to both maintaining nerve and muscle electrical potentials and transmitting impulses across neuromuscular junctions. Preliminary evidence shows magnesium may act as a neuroprotective agent in patients diagnosed with acute stroke. Several possible mechanisms of neuroprotection exist, including noncompetitive N-methyl-D-aspartate (NMDA) antagonism and calcium channel antagonism,
- Contributes to normal protein synthesis.

5.2. Pharmacokinetic properties

There is no clinical pharmacokinetic data available on NutriPure Magnesium Gummies to clarify the pharmacokinetic properties.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

carnauba wax,
citric acid,
citrus pectins,
coconut oil,
colourant,
fruit juice concentrate,
glucose syrup,
sodium citrate,
natural flavour (flavouring),
sucrose,
water.

6.2. Incompatibilities

None known.

6.3. Shelf life

The shelf life for NutriPure Magnesium Gummies is 24 months.

6.4. Special precautions for storage

Store at or below 25 °C in a cool, dry place.
KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

NutriPure Magnesium Gummies container is a white, shiny 300 ml, plastic PET bottle with a green, CRC cap and a silver induction liner containing 60 gummies.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MDI Healthcare cc
P.O. Box 35259,
Menlo Park,
Pretoria,
0102

Marketed by:
NutriPure Healthcare
P.O. Box 16645,
Vlaeberg,
8018,
Cape Town.

8. REGISTRATION NUMBER(S):

To be allocated.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT

April 2024.