PATIENT INFORMATION LEAFLET

SCHEDULING STATUS [S0]
Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:
VITAFEN® Magnesium Slow Release Tablets

Each tablet contains:

Ingredients	Elemental value	NRV% *
Magnesium (as Magnesium Bisglycinate and Magnesium Citrate)	64 mg	15

* South African Nutrient reference values for individuals 4 years and older.

Other ingredients:
Calcium Carbonate, Colloidal Silicon Dioxide, Dicalcium Phosphate, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Talc, Titanium Dioxide, Flexi-Coat® Red Coating Agent.
Contains no artificial sweeteners, lactose or sugar.

PHARMACOLOGICAL CLASSIFICATION
34.7 Category D (Health Supplement) [S0]

INDICATIONS
VITAFEN® Magnesium Slow Release Tablets provide the gradual release of magnesium over time.
Contributes to:

- The reduction of tiredness and fatigue.
- The maintenance of normal muscle function.
- Normal energy-yielding metabolism.
- Normal functioning of the nervous system.
- Normal protein synthesis.
- Normal electrolyte balance.
- Normal psychological function.
- Maintenance of normal bones and teeth.
- Tissue formation.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients. If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking this medicine.

WARNINGS AND SPECIAL PRECAUTIONS
Do not exceed the recommended dose. Follow all directions on your medicine label. Always tell your healthcare provider if you are taking any other medicine. If you have or had kidney disease, take extra precautions when taking this medicine.

Not recommended for children under the age of 9 years, unless under medical supervision.

KEEP OUT OF REACH OF CHILDREN.

INTERACTIONS
Magnesium, if taken together with other medication, may affect the absorption of medicines for the following conditions:

- Bisphosphonates, to treat osteoporosis, are not well absorbed when taken too soon before or after taking dietary supplements or medications with high amounts of magnesium.
- Antibiotics might not be absorbed if taken too soon before or after taking a dietary supplement that contains magnesium.
- Diuretics can either increase or decrease the loss of magnesium through urine, depending on the type of diuretic.
- Medicine used to ease symptoms of acid reflux or treat peptic ulcers can cause low blood levels of magnesium when taken over an extended period of time.
- Very high doses of zinc supplements can interfere with the body's ability to absorb and regulate magnesium.

Magnesium when consumed in large quantities, may interact with some blood pressure medication.
Always consult your healthcare professional if you are taking any other medicine.

DOSAGE AND DIRECTIONS FOR USE
Adults and children ≥ 9 years: Take 1 to 3 tablets per day, with a glass of water after a meal.

Do not share medicines prescribed for you with any other person. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE EFFECTS
Less severe side effects are:

- Upset stomach, vomiting and constipation.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any side effects while taking this medicine, please consult your health care provider for advice.

STORAGE INSTRUCTIONS
Close the container properly after usage. Store in a cool, dry place below 25 °C. Do not leave the container open or store it in a fridge.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION
Silver with Silver lid packaged container with tamperproof induction seal, a sponge and a silica gel sachet. Clearly labelled with detailed information printed on the label. Containing 60 or 100 tablets.

IDENTIFICATION
Red coated round convex tablets.

REGISTRATION NUMBER
To be allocated.

APPLICANT
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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET
July 2022

Complementary Medicine: Health Supplement
Classification D (HS)
This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

PASIËNT INLIGTINGSBLAADJIE

SKEDULERINGSTATUS [S0]

Nie geskeduleer nie

HANDELSNAAM EN DOSERINGSVORM:

VITAFEN® Magnesium Stadige Vrystelling Tablette

Elke tablet bevat:

Bestanddele	Elementêre waarde	NRV% *
Magnesium (as Magnesiumbisglisinaat en Magnesiumsitraat)	64 mg	15

* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer.

Ander bestanddele:

Kalsiumkarbonaat, Kolloïdale Silikondioksied, Dikalsiumfosfaat, Hipromellose, Magnesiumstearaat, Mikrokristalien Sellulose, Povidoon, Talk, Titaandioksied, Flexi-Coat® Rooi Deklaag Agent.

Bevat geen suiker, laktose of kunsmatige versoeter.

FARMAKOLOGIESE KLASSIFIKASIE

34.7 Kategorie D (Gesondheidsaanvuller) [S0]

INDIKASIES

VITAFEN® Magnesium Stadige Vrystelling tablette verskaf die geleidelike vrystelling van magnesium oor tyd.

Dra by tot:

- Die vermindering van moegheid en uitputting.
- Die handhawing van normale spierfunksie.
- Normale energie-opbrengs metabolisme.
- Normale funksionering van die senuweestelsel.
- Normale elektrolietbalans.
- Normale proteïensintese.
- Normale sielkundige funksie.
- Instandhouding van normale bene en tande.
- Weefselvorming.

KONTRA-INDIKASIES

Hipersensitiwiteit vir enige van die bestanddele. Indien swanger of borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat hierdie medisyne gebruik word.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Moenie die aanbevole dosis oorskry nie. Volg altyd die aanwysings op die etiket. Raadpleeg altyd u gesondheidsorgverskaffer indien u enige ander medikasie gebruik. As jy niersiekte het of gehad het, neem ekstra voorsorgmaatreëls wanneer jy hierdie medisyne neem.

Nie aanbeveel vir kinders onder die ouderdom van 9 jaar nie, tensy onder mediese toesig.

HOU BUITE BEREIK VAN KINDERS.

INTERAKSIES

Magnesium, as dit saam met ander medikasie geneem word, kan die absorpsie van medisyne vir die volgende toestande beïnvloed:

- Bisfosfonate, om osteoporose te behandel, word nie goed geabsorbeer wanneer dit te gou voor of na dieetaanvullings of medikasie met hoë hoeveelhede magnesium geneem word nie.
- Antibiotika mag dalk nie geabsorbeer word as dit te gou voor of na dieetaanvullings of medikasie wat magnesium bevat, geneem word nie.
- Diuretika kan die verlies van magnesium deur urine verhoog of verminder, afhangende van die tipe diuretikum.
- Teensuurmedisyne wat gebruik word om simptome van suur refluks te verlig of maagsere te behandel, kan lae bloedvlakke van magnesium veroorsaak wanneer dit oor 'n lang tydperk geneem word.
- Baie hoë dosisse sinkaanvullings kan inmeng met die liggaam se vermoë om magnesium te absorbeer en te reguleer.

Die gebruik van Magnesium in groot hoeveelhede, kan 'n interaksie toon met sekere bloeddruk medikasie. Raadpleeg altyd jou gesondheidswerker as jy enige ander medisyne gebruik.

DOSERING EN GEBRUIKSAANWYSINGS:

Volwassenes en kinders ≥ 9 jaar: Neem 1 tot 3 tablette daagliks, met 'n glas water na 'n maaltyd.

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

NEWE-EFFEKTE

Minder ernstige newe-effekte is:

- Maagongesteldheid of braking en hardlywigheid.

Nie alle newe-effekte is in hierdie pamflet gelys nie. Indien u algemene gesondheidstoestand versleg of as u enige newe-effekte ervaar, raadpleeg u gesondheidsorgverskaffer vir advies.

BERGINGSINSTRUKSIES

Verseël die houer behoorlik na gebruik. Bêre op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat of in die yskas bêre nie.

STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

AANBIEDING

Silwer met silwer deksel verpakte houer met peuterbestande induksie seël, 'n spons en 'n silikagel sakkie. 'n Gedrukte etiket met volledige aanwysings is op die houer aangebring. Bevat 60 of 100 tablette.

IDENTIFIKASIE

Rooi bedekte ronde konvekse tablette.

REGISTRASIE NOMMER

Om toegeken te word.

AANSOEKER

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® = Geregistreerde handelsmerk

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET

Julie 2022

Aanvullende Medisyne: Gesondheidsaanvuller

Klassifikasie: D (HS)

Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnosering, behandeling, genesing of voorkoming van enige siekte nie.