

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.7 Minerals

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### MAG CITRATE™, 120 Tablets

#### COMPOSITION

Each one (1) tablet of MAG CITRATE™ contains the following actives:

|                                  |        |
|----------------------------------|--------|
| Magnesium (as magnesium citrate) | 100 mg |
| Calcium (as calcium citrate)     | 20 mg  |

**Inactive ingredients:** Microcrystalline cellulose, croscarmellose sodium, cellulose, stearic acid (vegetable), and coating (hypromellose, mediumchain triglycerides, and hydroxypropylcellulose).

**This product is suitable for Vegetarians, is gluten and dairy free.**

**(Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

MAG CITRATE™ is a blend of magnesium citrate and calcium citrate that provides nutritional support for healthy muscle function. It also plays a role in bone health.

| Ingredients                      | Uses for ingredient  |
|----------------------------------|--|
| Magnesium (as magnesium citrate) | Magnesium is a mineral involved in many body processes. It assists with 300 different enzymes on which the body relies to build bone and regulates nerve function. |
| Calcium (as calcium citrate)     | Calcium citrate increases calcium levels in your body. Calcium is a mineral that plays an important role in building strong bones.                                 |

#### CONTRA INDICATIONS:

Caution is advised when taking Magnesium with hypertensive, diuretic and muscle relaxant medicines in order to avoid unwanted interactions. If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take MAG CITRATE™ if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : rectal bleeding, bowel problems (such as blockage, ulcerative colitis, hemorrhoids), heart disease (such as irregular heartbeat), kidney disease, current stomach/abdominal symptoms (such as nausea/vomiting that doesn't stop, pain, cramping), high calcium/vitamin D levels (hypercalcemia/hypervitaminosis D), difficulty absorbing nutrition from food (malabsorption syndrome), heart/blood vessel disease, kidney disease (including kidney stones), certain immune system disorder (sarcoidosis), liver disease, certain bowel diseases (Crohn's disease, Whipple's disease), little or no stomach acid (achlorhydria), low levels of bile, untreated phosphate imbalance. If you are taking the following medication, please consult with your healthcare professional before taking: digoxin, sodium polystyrene sulfonate, tetracycline/quinolone antibiotics (such as tetracycline, ciprofloxacin). If any of the following happens, stop using MAG CITRATE™ and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;
- no bowel movement within 6 hours after taking the medicine; pain with bowel movements, rectal bleeding; watery diarrhoea, nausea, vomiting, severe stomach pain; painful or difficult urination; flushing (warmth, redness, or tingly feeling); a light-headed feeling, like you might pass out; weak or shallow breathing, slow heartbeats; or muscle weakness, increased thirst.



These are all very serious effects. If you have them, you may have had a serious reaction to MAG CITRATE™. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, constipation, loss of appetite, mental/mood changes, unusual tiredness.

These are all very serious effects: If you have them, you may have had a serious reaction to MAG CITRATE™. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

#### DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

#### INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

#### DOSAGE AND DIRECTIONS FOR USE

**Adults:** Take one (1) tablet daily or as directed by your healthcare practitioner.

Take 2 hours before or 2 hours after antibiotics

**Do not take more than the recommended dose.**

#### SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

#### KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

#### Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

#### STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use MAG CITRATE™ if you notice visible signs of deterioration.

#### IDENTIFICATION

Coated white tablet.

#### PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

#### NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,

Sandton, 2146

Tel: 011-802-8101

#### DATE OF PUBLICATION

To be allocated by the regulatory authority.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.7 Minerale

HANDELSNAAM EN DOSEERVORM,

## MAG CITRATE™, 120 tablette

### SAMESTELING

**Elke (1) tablet MAG CITRATE™ bevat die volgende aktiewe stowwe:**

|                                 |        |
|---------------------------------|--------|
| Magnesium (as magnesiumsitraat) | 100 mg |
| Kalsium (as kalsiumsitraat)     | 20 mg  |

**Onaktiewe bestanddele:** Mikrokristallyn-sellulose, kroskarmellose-natrium, sellulose, steariensuur (plant), en bedekking (hipromellose, mediumketting trigliseriede, en hidroksiopropielsellulose).

**Hierdie produk is geskik vir vegetariërs, is gluten- en suiwelvry.**

(Suiker vry)

### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**MAG CITRATE™** is 'n mengsel van magnesiumsitraat en kalsiumsitraat wat voedingsondersteuning bied vir gesonde spierfunksie. Dit speel ook 'n rol in beegesondheid.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **MAG CITRATE™** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlus, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **MAG CITRATE™** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind.

Lees hierdie inligtingsblad aandagdig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

• Hou hierdie inligtingsblad. Miskien moet u dit weer lees.

• Moenie medisyne met enige ander persoon deel nie.

• Vra jou apteker of jy meer inligting of advies benodig.

• Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

• As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

• Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

### INTERAKSIE

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

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### DOSIS EN AANWYSINGS VIR GEBRUIK

**Volwasse:** Neem een (1) tablet daaglik of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige

effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg

asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir

raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad

genoem word nie, stel asseblief jou dokter, apteker of

gesondheidsorgpraktisyn in kennis.

### BEKENE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

**Sien behandelings:**

Staak gebruik en raadpleeg jou dokter, apteker of ander

gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui

word nie.

Moenie **MAG CITRATE™** gebruik as u sigbare tekens van agteruitgang

opmerk nie.

### IDENTIFIKASIE

Bedekte wit tablet.

### AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseël,

peutekrimpseël, spons en silikagelsakke.

### REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit,

veiligheid of beoogde gebruik nie.

### NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur: Ampiro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146.

Tel: 011- 802-8101

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

| Bestanddele                     | Gebruike vir bestanddeel   |
|---------------------------------|--|
| Magnesium (as magnesiumsitraat) | Magnesium is 'n mineraal wat by baie liggaamsproesse betrokke is. Dit help met 300 verskillende ensieme waarop die liggaam staatmaak om been te bou en senuweefunksie te reguleer. |
| Kalsium (as kalsiumsitraat)     | Kalsiumsitraat verhoog kalsiumvlakke in jou liggaam. Kalsium is 'n mineraal wat 'n belangrike rol speel in die bou van sterk bene.   |

### KONTRA-INDIKASIES:

Wees versigtig wanneer Magnesium saam met hipertensiewe, diuretiese en

spierverslappende medisyne geneem word om ongewenste interaksies te

vermy. As jy enige chroniese medisyne neem, moenie hierdie produk gebruik

sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **MAG**

**CITRATE™** neem as jy hipersensitief (allergies) is vir enige van die bestanddele

nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn

gaan voordat jy hierdie aanvulling neem.

### WAARSKUWING EN SPEZIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou

gesondheidsorgpraktisyn voor gebruik: rektale bloeding, dermprobleme (soos

verstopping, ulseratiewe kolitis, aambeie), hartsiektes (soos onreëlmatige

hartklop), niersiekte, huidige maag / abdominale simptome (soos naarheid /

braking wat nie ophou nie, pyn, krampe), hoë kalsium / vitamien D-vlakke

(hiperkalsemie / hipervitaminoos D), probleme om voeding uit voedsel te

absorbeer (wanabsorpsiesindroom), hart-/bloedvatsiekte, niersiekte

(insluitend nierstene), sekere immuunstelselversteuring (sarkoidose),

lwersiekte, sekere dermsiektes (Crohn se siekte, Whipple se siekte), min of

geen maagsuur (achlorhidrie), lae vlakke van gal, onbehandelde

fosfaatwanbalans.

As jy die volgende medisyne neem, raadpleeg asseblief jou

gesondheidspraktisyn voordat jy neem: digoksin,

natriumpolistireensulfonaat, tetrasiklien/kinolonantibiotika (soos tetrasiklien,

profloksacin). As enige van die volgende gebeur, hou op om **MAG CITRATE™**

te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste

hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling.;
- geen stoelgang binne 6 uur nadat die medisyne geneem is nie; pyn met dermbewegings, rektale bloeding; waterige diarree, naarheid, braking, erge maagpyn; pylilke of moeilike urinering; blos (warmte, rootheid of tintelende gevoel); 'n lighoofdigte gevoel, asof jy kan flou word; swak of vlak asemhaling, hartdigte klop; of spierswakheid, verhoogde dorstheid.