

PROFESSIONAL INFORMATION

D 34.7 Minerals. Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH MAGNESIUM capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Magnesium Amino Acid Chelate 10%	500 mg
Of which elemental Magnesium	10 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Size 0, red capsules containing a white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Magnesium contributes to normal energy-yielding metabolism and electrolyte balance, the functioning of the nervous system, and to the reduction of tiredness and fatigue. It contributes to the maintenance of normal muscle function, the synthesis of protein and the process of cell division. It contributes to the maintenance of normal bones, teeth and tissue formation.

4.2 Posology and method of administration

Adults and children 6 years and older: one (1) capsule twice daily.

4.3 Contraindications

Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Hypermagnesemia can cause heart block.
- Patients with renal impairment should use magnesium supplements cautiously due to an increased risk of hypermagnesemia.

4.5 Interaction with other medicines and other forms of interaction

- Use of aminoglycoside antibiotics and magnesium concomitantly can lead to neuromuscular weakness and possible paralysis.
- Magnesium can form insoluble complexes with tetracycline and quinolones in the gut and decrease their absorption and antibacterial activity. Patients should take tetracycline antibiotics at least 2 hours before, or 4 hours after magnesium supplements.
- Magnesium-based antacids can elevate gastrointestinal pH, leading to increased solubility and enhanced absorption of sulfonyleureas. Concomitant use of sulfonyleureas and magnesium-based antacids may theoretically increase the risk of hypoglycemia in some patients.
- Magnesium can decrease bisphosphonate absorption. Patients should separate doses by at least 2 hours.
- Magnesium inhibits calcium entry into smooth muscle cells and may therefore have additive effects with calcium channel blockers.
- Magnesium may reduce the absorption of digoxin from the intestine, thereby reducing blood levels of digoxin and decrease its therapeutic effects.
- Magnesium can reduce the effectiveness of levodopa/carbidopa when taken together. Patients should avoid taking levodopa/carbidopa in conjunction with magnesium.

4.6 Fertility, pregnancy and lactation

Magnesium is likely safe when taken within normal, recommended dosages.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH MAGNESIUM does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal

Less frequent: gastrointestinal irritation, nausea, vomiting and diarrhoea.

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. Health care 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

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Magnesium is an essential mineral that contributes to normal energy-yielding metabolism and electrolyte balance, the functioning of the nervous system, and to the reduction of tiredness and fatigue. It contributes to the maintenance of normal muscle function, the synthesis of protein and the process of cell division. It contributes to the maintenance of normal bones, teeth and tissue formation.

5.2 Pharmacokinetic properties

Magnesium requires parathyroid hormone and vitamin D for absorption. Magnesium is absorbed throughout the gastrointestinal tract. Whether maximal absorption occurs in the duodenum or colon is unclear. Absorption occurs mainly by intercellular diffusional and solvent drag mechanisms. Approximately one third of dietary magnesium is absorbed and the fraction of magnesium absorbed increases as magnesium intake decreases. In plasma, about 25-30% of magnesium is protein bound. Oral doses of magnesium are eliminated in the urine and in the faeces. Small amounts are distributed into breast milk. Magnesium crosses the placenta.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicon dioxide, maize starch, magnesium stearate, sea salt.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

60 capsules in a white, PET plastic container and white screwcap lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjsa.com

011 589 2729

www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

S0
LOCAL HEALTH MAGNESIUM (capsules)

Each capsule contains:	
Magnesium Amino Acid Chelate 10%	500 mg
Of which elemental Magnesium	10 mg
Sugar free	

Complementary Medicine: Minerals (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

Read all of this leaflet carefully because it contains important information for you.

LOCAL HEALTH MAGNESIUM is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH MAGNESIUM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH MAGNESIUM with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH MAGNESIUM is and what it is used for.
2. What you need to know before you use LOCAL HEALTH MAGNESIUM.
3. How to use LOCAL HEALTH MAGNESIUM.
4. Possible side effects.
5. How to store LOCAL HEALTH MAGNESIUM.
6. Contents of the pack and other information.

1. What LOCAL HEALTH MAGNESIUM is and what it is used for

Magnesium contributes to normal energy-yielding metabolism and electrolyte balance, the functioning of the nervous system, and to the reduction of tiredness and fatigue. It contributes to the maintenance of normal muscle function, the synthesis of protein and the process of cell division. It contributes to the maintenance of normal bones, teeth and tissue formation.

2. What you need to know before you use LOCAL HEALTH MAGNESIUM

Do not use LOCAL HEALTH MAGNESIUM:

- If you are allergic or sensitive to any of the ingredients listed in section 6.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH MAGNESIUM, especially if you have a medical condition.

Use LOCAL HEALTH MAGNESIUM with caution and consult a healthcare practitioner before use:

- If you have heart block or renal impairment.

Children and adolescents

LOCAL HEALTH MAGNESIUM is not recommended for children below the age of 6 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH MAGNESIUM

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH MAGNESIUM may interact with the following medications: aminoglycoside antibiotics, tetracycline antibiotics, quinolone antibiotics, antacids, bisphosphonates, calcium channel blockers, digoxin, and levodopa/carbidopa.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH MAGNESIUM.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH MAGNESIUM does not adversely affect their performance.

3. How to use LOCAL HEALTH MAGNESIUM

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH MAGNESIUM exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 6 years and older:

Take one (1) capsule twice daily, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH MAGNESIUM can have side effects. Not all side effects reported for LOCAL HEALTH MAGNESIUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH MAGNESIUM, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH MAGNESIUM and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH MAGNESIUM. You may need urgent medical attention or hospitalisation.

- **Less frequent:** gastrointestinal irritation, nausea, vomiting and diarrhoea.
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH MAGNESIUM.

5. How to store LOCAL HEALTH MAGNESIUM

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH MAGNESIUM to your pharmacist.
- Do not dispose of unused LOCAL HEALTH MAGNESIUM in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH MAGNESIUM contains

Each capsule contains:	
Magnesium Amino Acid Chelate 10%	500 mg
Of which elemental Magnesium	10 mg

Other ingredients: silicon dioxide, maize starch, magnesium stearate, sea salt.
Sugar free

Presentation and identification of LOCAL HEALTH MAGNESIUM

60, size 0 red capsules packed into a white plastic container.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

S0
LOCAL HEALTH MAGNESIUM (kapsules)

Elke kapsule bevat:	
Magnesium Aminosuurcheelaat 10%	500 mg
Waarvan elementele Magnesium	10 mg
Suikervry	

Komplementêre Medisyne: Minerale (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH MAGNESIUM is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH MAGNESIUM versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH MAGNESIUM met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH MAGNESIUM is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH MAGNESIUM gebruik.
3. Hoe om LOCAL HEALTH MAGNESIUM te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH MAGNESIUM.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH MAGNESIUM is en waarvoor dit gebruik word

Magnesium dra by tot die normale energie-gewende metabolisme en elektrolietbalans, die werking van die senuweestelsel, en tot die vermindering van moegheid en tamheid. Dit dra by tot die handhawing van normale spierfunksie, die sintese van proteïene en die proses van seldeling. Dit dra by tot die instandhouding van normale bene, tande en weefselvorming.

2. Wat u moet weet voordat u LOCAL HEALTH MAGNESIUM gebruik

Moet nie LOCAL HEALTH MAGNESIUM neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH MAGNESIUM gebruik, veral as u 'n mediese toestand het.

Gebruik LOCAL HEALTH MAGNESIUM met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u hartblok of nierontoereikenheid het.

Kinders en adolessente

LOCAL HEALTH MAGNESIUM word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH MAGNESIUM en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH MAGNESIUM kan interaksie hê met die volgende medisyne: aminoglikosied-antibiotika, tetraskilien-antibiotika, kinolon-antibiotika, teensuurmiddels, bisfosfonate, kalsiumkanaalblokkers, digoksien, en levodopa / carbidopa.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH MAGNESIUM gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH MAGNESIUM nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH MAGNESIUM te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH MAGNESIUM presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 6 jaar en ouer:

Neem een (1) kapsule twee maal daagliks, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH MAGNESIUM kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH MAGNESIUM is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH MAGNESIUM, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH MAGNESIUM en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejeuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH MAGNESIUM gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Minder dikwels:** gastrointestinale irritasie, naarheid, braking en diarree.
- Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van LOCAL HEALTH MAGNESIUM.

5. Berging van LOCAL HEALTH MAGNESIUM

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BUIE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket terug.
- Neem alle ongebruikte LOCAL HEALTH MAGNESIUM na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH MAGNESIUM in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH MAGNESIUM bevat

Elke kapsule bevat:	
Magnesium Aminosuurcheelaat 10%	500 mg
Waarvan elementele Magnesium	10 mg

Ander bestanddele: silikondioksied, mieliestysel, magnesiumstearaat, seesout.

Suikervry

Aanbieding en identifikasie van LOCAL HEALTH MAGNESIUM

60 rooi, grootte 0 kapsules, verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hiersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.