

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH SLOW RELEASE MAGNESIUM tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Magnesium Sulphate Dihydrate	440 mg
Providing Magnesium (elemental)	68,4 mg
Dicalcium Phosphate	230 mg
Providing Calcium (elemental)	67,7 mg
Providing Phosphorus (elemental)	52,4 mg

Contains sugar: mannitol (110 mg) per tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, reddish-pink coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH SLOW RELEASE MAGNESIUM contains magnesium which contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.

4.2 Posology and method of administration

Adults and children 9 years and older: Take two to three tablets daily.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

- Kidney disease reduces magnesium excretion and increases the risk for hypermagnesemia.
- Serum electrolytes should be closely monitored when phosphates are used by people with mild to moderate kidney impairment.
- Sarcoidosis results in an increased risk of excessive calcium absorption and hypercalcemia.

4.5 Interaction with other medicines and other forms of interaction

- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness. However, this is most likely to occur with high doses of magnesium given intravenously.
- Magnesium and calcium can decrease absorption of bisphosphonates, tetracyclines, quinolones and gabapentin.
- Taking calcipotriene with calcium may increase the risk of hypercalcemia.
- Calcium may reduce levels of dolutegravir, elvitegravir and raltegravir.
- Calcium carbonate supplements reduce effectiveness of levothyroxine in those with hypothyroidism when taken concomitantly.
- Calcium appears to reduce the absorption of sotalol when taken concomitantly.
- Magnesium salts may reduce absorption of digoxin and its therapeutic effects.
- Magnesium may precipitate ketamine toxicity.
- Magnesium can reduce the bioavailability of levodopa/carbidopa.
- Potassium-sparing diuretics also have magnesium-sparing properties, which decrease excretion of magnesium and possibly increasing magnesium levels.
- Magnesium increases systemic absorption of sulfonyleureas, increases their effects and side effects.
- Taking erdafitinib with phosphate salts increases the risk of hyperphosphatemia. It is recommended that patients taking erdafitinib restrict phosphate intake to no more than 600-800 mg daily.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

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 SLOW RELEASE MAGNESIUM does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

Frequent: diarrhoea, gastrointestinal irritation, abdominal pain, nausea, vomiting, flatulence, belching, anal irritation.

Metabolic and nutrition disorders

Frequency unknown: electrolyte disturbances including hyperphosphatemia, hypocalcemia, extraskeletal calcification.

Neurological disorders

Frequency unknown: malaise, headaches, sleep disturbances.

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 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

Category and class: D 34.7 Minerals.

5.1 Pharmacodynamic properties

LOCAL HEALTH SLOW RELEASE MAGNESIUM contains magnesium which contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH SLOW RELEASE MAGNESIUM.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl dibehenate
Magnesium stearate
Nutrafinish Red film-coating
Polyvinylpyrrolidone
Mannitol

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.

6.5 Nature and contents of container

White plastic bottle with a white plastic lid.

Pack size: 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

010 589 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 SLOW RELEASE MAGNESIUM (tablets)

Each tablet contains:	
Magnesium Sulphate Dihydrate	440 mg
Providing Magnesium (elemental)	68,4 mg
Dicalcium Phosphate	230 mg
Providing Calcium (elemental)	67,7 mg
Providing Phosphorus (elemental)	52,4 mg
Contains sugar: mannitol (110 mg) per tablet.	

Complementary Medicine: Minerals (Health Supplement)

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH SLOW RELEASE 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 SLOW RELEASE MAGNESIUM is and what it is used for.
2. What you need to know before you use LOCAL HEALTH SLOW RELEASE MAGNESIUM.
3. How to use LOCAL HEALTH SLOW RELEASE MAGNESIUM.
4. Possible side effects.
5. How to store LOCAL HEALTH SLOW RELEASE MAGNESIUM.
6. Contents of the pack and other information.

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

LOCAL HEALTH SLOW RELEASE MAGNESIUM contains magnesium which contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.

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

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

Do not use LOCAL HEALTH SLOW RELEASE MAGNESIUM:

- If you are hypersensitive (allergic) to any of the ingredients listed in section 6.

Warnings and precautions

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

Consult a healthcare practitioner prior to use:

- If you have a kidney disease or renal impairment.
- If you have sarcoidosis.

Children and adolescents

LOCAL HEALTH SLOW RELEASE MAGNESIUM is not recommended for individuals below the age of 9 years.

Other medicines and LOCAL HEALTH SLOW RELEASE 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 if you are taking any other medication.

Consult a healthcare practitioner prior to use if you are taking any of the following medications: aminoglycoside antibiotics, bisphosphonates, tetracyclines, quinolones, gabapentin, calcipotriene, dolutegravir, elvitegravir, raltegravir, levothyroxine, sotalol, digoxin, ketamine, levodopa/carbidopa, potassium-sparing diuretics, sulfonylureas, erdafitinib.

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 SLOW RELEASE 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 SLOW RELEASE MAGNESIUM does not adversely affect their performance.

3. How to use LOCAL HEALTH SLOW RELEASE MAGNESIUM

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH SLOW RELEASE 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 9 years and older

Take two to three tablets daily, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH SLOW RELEASE MAGNESIUM can have side effects. Not all side effects reported for LOCAL HEALTH SLOW RELEASE MAGNESIUM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH SLOW RELEASE MAGNESIUM, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH SLOW RELEASE MAGNESIUM and tell your doctor or pharmacist immediately, or go to 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 SLOW RELEASE MAGNESIUM. You may need urgent medical attention or hospitalisation.

Frequent: diarrhoea, gastrointestinal irritation, abdominal pain, nausea, vomiting, flatulence, belching, anal irritation.

Frequency unknown: electrolyte disturbances including hyperphosphatemia, hypocalcemia, extraskeletal calcification, malaise, headaches, sleep disturbance.

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 SLOW RELEASE MAGNESIUM.

5. How to store LOCAL HEALTH SLOW RELEASE MAGNESIUM

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

6. Contents of the pack and other information

What LOCAL HEALTH SLOW RELEASE MAGNESIUM contains

Each tablet contains:	
Magnesium Sulphate Dihydrate	440 mg
Providing Magnesium (elemental)	68,4 mg
Dicalcium Phosphate	230 mg
Providing Calcium (elemental)	67,7 mg
Providing Phosphorus (elemental)	52,4 mg
Other ingredients: glyceryl dibehenate, magnesium stearate, Nutrafinish Red film-coating, polyvinylpyrrolidone, mannitol.	
Contains sugar: mannitol (110 mg) per tablet.	

Presentation and identification of LOCAL HEALTH SLOW RELEASE MAGNESIUM

Round, reddish-pink coated tablets, packed into a white plastic container with a white plastic lid. Pack size: 100 tablets.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 010 589 2729; careline@cjdjsa.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 SLOW RELEASE MAGNESIUM (tablette)

Elke tablet bevat:	
Magnesiumsulfaatdihidraat	440 mg
Verskaf Magnesium (elementale)	68,4 mg
Dikalsiumfosfaat	230 mg
Verskaf Kalsium (elementale)	67,7 mg
Verskaf Fosfor (elementale)	52,4 mg
Bevat suiker: mannitol (110 mg) per tablet.	

Komplementêre Medisyne: Minerale (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie.

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

LOCAL HEALTH SLOW RELEASE MAGNESIUM is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemin moet LOCAL HEALTH SLOW RELEASE 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 SLOW RELEASE 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 SLOW RELEASE MAGNESIUM is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH SLOW RELEASE MAGNESIUM gebruik.
3. Hoe om LOCAL HEALTH SLOW RELEASE MAGNESIUM te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om LOCAL HEALTH SLOW RELEASE MAGNESIUM te bêre.
6. Inhoud van die verpakking en ander inligting

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

LOCAL HEALTH SLOW RELEASE MAGNESIUM bevat magnesium wat dra by tot normale energiegewende metabolisme, normale elektrolietbalans, en die handhaving van normale spier- en sensuuewustelsel funksie. Kalsium en fosfor dra by tot die ontwikkeling en instandhouding van bene en tande.

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

'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling, sowel as geestelike en fisiese prestasie te behaal.

Moet nie LOCAL HEALTH SLOW RELEASE MAGNESIUM neem nie:

- Indien u hipersensitief (allergies) is vir enige van die bestanddele gelys in afdeling 6.

Waarskuwings en voorsorgmaatreëls

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

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u 'n nier siekte of nierontoereiktheid het.
- Indien u sarkoïdose het.

Kinders en adolessente

LOCAL HEALTH SLOW RELEASE MAGNESIUM word nie aanbeveel vir individue onder die ouderdom van 9 jaar nie.

Die neem van LOCAL HEALTH SLOW RELEASE 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 indien u enige ander medikasie gebruik.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik indien u enige van die volgende medisyne neem: aminoglikosied antibiotika, bisfosfonate, tetrasikline, kinolone, gabapentien, kalsipotriene, dolutegravir, elvitegravir, raltegravir, levotiroksien, sotalol, digoksien, ketamien, levodopa/carbidopa, kaliumbesparende diuretika, sulfonylureas, erdafitinib.

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 SLOW RELEASE 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 SLOW RELEASE MAGNESIUM nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH SLOW RELEASE 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 SLOW RELEASE 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 9 jaar en ouer

Neem twee tot drie tablette daaglik, of soos aanbeveel deur u gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH SLOW RELEASE MAGNESIUM kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH SLOW RELEASE 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 SLOW RELEASE MAGNESIUM, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van LOCAL HEALTH SLOW RELEASE MAGNESIUM en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevallen afdeling van u naaste hospitaal: swelling van u 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 u dit het, mag u 'n ernstige allergiese reaksie teen LOCAL HEALTH SLOW RELEASE MAGNESIUM gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Dikwels: diarree, gastroïntestinale irritasie, buikpyn, naarheid, braking, winderigheid, winde opbreek, anale irritasie.

Dikwelsheid onbekend: elektrolietversteurings insluitend hiperfosfatemie, hipokalsemie, ekstraskelatale verkalking, malaise, hoofpyn, slaapprobleme.

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 SLOW RELEASE MAGNESIUM.

5. Hoe om LOCAL HEALTH SLOW RELEASE MAGNESIUM te bêre

- Beskerm teen vog en bêre by of onder 25 °C.
- HOU BUITE BEREIK VAN KINDERS.
- Stoor in die oorspronklike verpakking en hou die houder dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH SLOW RELEASE MAGNESIUM na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH SLOW RELEASE MAGNESIUM in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH SLOW RELEASE MAGNESIUM bevat

Elke tablet bevat:	
Magnesiumsulfaatdihidraat	440 mg
Verskaf Magnesium (elementale)	68,4 mg
Dikalsiumfosfaat	230 mg
Verskaf Kalsium (elementale)	67,7 mg
Verskaf Fosfor (elementale)	52,4 mg

Ander bestanddele: gliseriëdibehenaat, magnesiumstearaat, Nutrafinish Red filmbedekking, polivinilpirolidoon, mannitol.

Bevat suiker: mannitol (110 mg) per tablet.

Aanbieding en identifikasie van LOCAL HEALTH SLOW RELEASE MAGNESIUM

Ronde, rooierig-pienk bedekte tablette, verpak in 'n wit plastiekhouer met 'n wit plastiek deksel. Verpakkingsgrootte: 100 tablette.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 010 589 2729; careline@cjdjsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.