

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 MAGNESIUM FIZZY effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

Magnesium Oxide	242,37 mg
Magnesium Citrate	221 mg
Providing Magnesium (elemental)	175 mg
Ascorbic Acid (Vitamin C)	150 mg

Contains sugar: sorbitol (530 mg) and isomalt (200 mg) per effervescent tablet.

Contains sweetener: acesulfame-K and sucralose blend (19 mg) per effervescent tablet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.

Flat, round, bevelled-edged effervescent tablets with a raspberry flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LOCAL HEALTH MAGNESIUM FIZZY contributes to the maintenance of normal muscle function, protein synthesis and tissue formation, to the normal function of the nervous system and towards the reduction of tiredness and fatigue.

4.2 Posology and method of administration

Adults and children 9 years and older: one effervescent tablet daily, dissolved in a glass of water.

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

- Caution should be advised in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, kidney disease, or a history of oxalate kidney stone formation.
- Patients with sarcoidosis.
- Patients at increased risk of hyperkalemia, such as those with kidney disease, heart failure, and adrenal insufficiency.

4.5 Interaction with other medicines and other forms of interaction

- Vitamin C may reduce the activity of warfarin.
- Iron excretion induced by desferrioxamine is enhanced by the administration of vitamin C.
- Vitamin C may increase plasma estrogen levels of estrogen-containing oral contraceptives.
- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Magnesium can decrease absorption of bisphosphonates and doses should be separated by at least 2 hours.
- Magnesium can reduce the bioavailability of levodopa/carbidopa.
- Magnesium decreases absorption of quinolone and tetracycline antibiotics, by forming insoluble complexes in the gut.

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 MAGNESIUM FIZZY does not adversely affect their performance.

4.8 Undesirable effects

Gastrointestinal disorders

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

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

Category and class: D 34.12 Multiple Substance Formulation.

5.1 Pharmacodynamic properties

LOCAL HEALTH MAGNESIUM FIZZY contributes to the maintenance of normal muscle function, protein synthesis and tissue formation, to the normal function of the nervous system and towards the reduction of tiredness and fatigue.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on LOCAL HEALTH MAGNESIUM FIZZY.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Sodium bicarbonate
Sorbitol
Flavouring
Isomalt
Tartaric acid
Polyethylene glycol
Crospovidone
Polyvinylpyrrolidone
Sucralose
Acesulfame-K
Colourant

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

Plastic tubes of 10 effervescent tablets, with a desiccant cap, packed into an outer carton. Pack size: 10 or 30 effervescent 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@cjsa.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 MAGNESIUM FIZZY (effervescent tablets)

Each effervescent tablet contains:

Magnesium Oxide	242,37 mg
Magnesium Citrate	221 mg
Providing Magnesium (elemental)	175 mg
Ascorbic Acid (Vitamin C)	150 mg

Contains sugar: sorbitol (530 mg) and isomalt (200 mg) per effervescent tablet.

Contains sweetener: acesulfame-K and sucralose blend (19 mg) per effervescent tablet.

Complementary Medicine: Multiple Substance Formulation (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 MAGNESIUM FIZZY is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH MAGNESIUM FIZZY carefully to get the best results from it.

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

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

LOCAL HEALTH MAGNESIUM FIZZY contributes to the maintenance of normal muscle function, protein synthesis and tissue formation, to the normal function of the nervous system and towards the reduction of tiredness and fatigue.

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

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 MAGNESIUM FIZZY:

- 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 MAGNESIUM FIZZY, especially if you have a medical condition.

Consult a healthcare practitioner prior to use:

- If you suffer from glucose-6-phosphate dehydrogenase (G6PD) deficiency, kidney disease, or a history of oxalate kidney stone formation.
- If you have sarcoidosis.
- If you are at an increased risk of hyperkalemia, such as those with kidney disease, heart failure, and adrenal insufficiency.

Children and adolescents

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

Other medicines and LOCAL HEALTH MAGNESIUM FIZZY

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. LOCAL HEALTH MAGNESIUM FIZZY may interact with the following medication: warfarin, desferrioxamine, oral contraceptives, aminoglycoside antibiotics, bisphosphonates, levodopa/carbidopa, quinolone and tetracycline antibiotics.

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 FIZZY.

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 FIZZY does not adversely affect their performance.

3. How to use LOCAL HEALTH MAGNESIUM FIZZY

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH MAGNESIUM FIZZY 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 one effervescent tablet daily, dissolved in a glass of water, or as recommended by your healthcare practitioner.

4. Possible side effects

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

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

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 FIZZY.

5. How to store LOCAL HEALTH MAGNESIUM FIZZY

- 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 MAGNESIUM FIZZY to your pharmacist.
- Do not dispose of unused LOCAL HEALTH MAGNESIUM FIZZY in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH MAGNESIUM FIZZY contains

Each effervescent tablet contains:

Magnesium Oxide	242,37 mg
Magnesium Citrate	221 mg
Providing Magnesium (elemental)	175 mg
Ascorbic Acid (Vitamin C)	150 mg

Other ingredients: citric acid, sodium bicarbonate, sorbitol, flavouring, isomalt, tartaric acid, polyethylene glycol, crospovidone, polyvinylpyrrolidone, sucralose, acesulfame-K, colourant.

Contains sugar: sorbitol (530 mg) and isomalt (200 mg) per effervescent tablet.

Contains sweetener: acesulfame-K and sucralose blend (19 mg) per effervescent tablet.

Presentation and identification of LOCAL HEALTH MAGNESIUM FIZZY

Plastic tubes of 10 effervescent tablets with a raspberry flavour, with a desiccant cap, packed into an outer carton.

Pack size: 10 or 30 effervescent tablets.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685

Careline: 010 589 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 FIZZY (bruisette)

Elke bruisette bevat:

Magnesiumoksied	242,37 mg
Magnesiumsitraat	221 mg
Verskaf Magnesium (elementale)	175 mg
Askorbiensuur (Vitamien C)	150 mg

Bevat suiker: sorbitol (530 mg) en isomalt (200 mg) per bruisette.

Bevat versoeter: acesulfame-K en sukralose mengsel (19 mg) per bruisette.

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

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

LOCAL HEALTH MAGNESIUM FIZZY dra by tot die handhawing van normale spierfunksie, proteïensintese en weefselvorming, die normale funksie van die senuweestelsel, en tot die vermindering van tamheid en moegheid.

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

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

Moet nie LOCAL HEALTH MAGNESIUM FIZZY 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 MAGNESIUM FIZZY gebruik, veral as u 'n mediese toestand het.

Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u ly aan glukose-6-fosfaat dehidrogenase (G6PD) tekort, niersiekte, of 'n geskiedenis van oksalaat nierstene het.
- Indien u sarkoidose het.
- Indien u 'n verhoogde risiko van hiperkalemie het, soos dié met niersiekte, hartversaking en adrenal ontoereikendheid.

Kinders en adolessente

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

Die neem van LOCAL HEALTH MAGNESIUM FIZZY 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. LOCAL HEALTH MAGNESIUM FIZZY kan interaksie hê met die volgende medikasie: warfarin, desferrioksamien, orale voorbehoedmiddels, aminoglykosied antibiotika, bisfosfonate, levodopa/karbidopa, kinoloon en tetrasiklien antibiotika.

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 FIZZY 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 FIZZY nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH MAGNESIUM FIZZY 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 FIZZY 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 een bruisette daaglik, opgelos in 'n glas water, of soos aanbeveel deur u gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH MAGNESIUM FIZZY kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH MAGNESIUM FIZZY 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 FIZZY, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik van LOCAL HEALTH MAGNESIUM FIZZY 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, gejuuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie teen LOCAL HEALTH MAGNESIUM FIZZY gehad het. U mag dringende mediese bystand of hospitalisasie nodig hê.

Dikwels: buikpyn, esofagitis, sooi-brand, winde opbreek, diarree, winderigheid, naarheid, braking, gastroïntestinale irritasie.

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 FIZZY.

5. Hoe om LOCAL HEALTH MAGNESIUM FIZZY 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 houer dig verseël.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH MAGNESIUM FIZZY na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH MAGNESIUM FIZZY in afvoertype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH MAGNESIUM FIZZY bevat

Elke bruisette bevat:

Magnesiumoksied	242,37 mg
Magnesiumsitraat	221 mg
Verskaf Magnesium (elementale)	175 mg
Askorbiensuur (Vitamien C)	150 mg

Ander bestanddele: sitroensuur, natriumbikarbonaat, sorbitol, geurmiddel, isomalt, wynsteensuur, poliëtileenglikol, crospovidone, polivinilpirrolidoon, sukralose, acesulfame-K, kleurstof.

Bevat suiker: sorbitol (530 mg) en isomalt (200 mg) per bruisette.

Bevat versoeter: acesulfame-K en sukralose mengsel (19 mg) per bruisette.

Aanbieding en identifikasie van LOCAL HEALTH MAGNESIUM FIZZY

Plastiekbuise van 10 bruisette met 'n framboosgeur, met 'n droogmiddel deksel, verpak in 'n buitenste karton.

Verpakkingsgrootte: 10 of 30 bruisette.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685

Sorgly: 010 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.