BIOGEN
FOR THE RESULTS YOU WANT

MAGNESIUM FIZZY

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
BIOGEN MAGNESIUM FIZZY (effervescent tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:		***%NRV**
Total Magnesium (elemental)	200,00 mg	48 %
From Magnesium Oxide	235,59 mg	
Magnesium Glycinate	200,00 mg	
Magnesium Citrate	158,62 mg	
Vitamin C (as Ascorbic Acid)	150,00 mg	200 %

Contains sugar: 300 mg sorbitol and 250 mg isomalt per effervescent tablet.
Contains sweetener: 21 mg sucralose 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
BIOGEN MAGNESIUM FIZZY support optimal muscle health, enhance muscle recovery, and strengthen the immune system.

4.2 Posology and method of administration

Posology
Adults and children 9 years and older:
Take 1 (one) tablet daily, dissolved in a glass of water, with or after food, or as directed by your healthcare provider.

Paediatric population
BIOGEN MAGNESIUM FIZZY is not recommended for individuals below the age of 9 years.

Method of administration
For oral use.
Dissolve in a glass of water.
To be taken with or after food.

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

4.4 Special warnings and precautions for use
Special care should be taken with BIOGEN MAGNESIUM FIZZY. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:
- 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.

Paediatric population
Not suitable for children below the age or 9 years unless under the direct supervision of a healthcare provider.

4.5 Interactions with other medicines and other forms of interactions
No interaction studies have been conducted on BIOGEN MAGNESIUM FIZZY. Always tell your healthcare professional if you are taking any other medicine. This includes all complementary or traditional medicines:
- Magnesium can bind with certain medications, preventing their full absorption.
- Magnesium can decrease the absorption of tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), take separate doses at least 2 hours before or 4-6 hours after a magnesium-containing supplement.
- Magnesium can decrease the absoprtion of bisphosphonate (for example, alendronate), thyroid medication (for example, levothyroxine), or quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), take separate doses at least 2 hours before or after taking a magnesium-containing supplement.
- Magnesium can reduce the bioavailability of levodopa / carbidopa, take separate doses.
- Potassium-sparing diuretics decrease excretion of magnesium, possibly increasing magnesium level.
- Vitamin C may reduce the activity of warfarin.
- Oral contraceptives (containing estrogens): may reduce blood levels of ascorbic acid; large doses (>1 g) of vitamin C may increase plasma oestrogen levels (possibly converting low-dose oral contraceptive to high-dose oral contraceptive); possibly breakthrough bleeding associated with withdrawal of high-dose vitamin C.

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 BIOGEN MAGNESIUM FIZZY does not adversely affect their performance.

4.8 Undesirable effects
BIOGEN MAGNESIUM FIZZY is generally well tolerated but may cause gastrointestinal discomfort in some patients.

Gastrointestinal disorders: *Frequency unknown:* Diarrhoea, gastrointestinal irritation, nausea, and vomiting.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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

5.1 Pharmacodynamic properties
Class and category: D 34.12 Multiple substance formulation.

Magnesium:
- Contributes to normal energy -yielding metabolism
- Contributes to normal functioning of the nervous system
- Contributes to the development and maintenance of bones and teeth
- Contributes to normal electrolyte balance
- Contributes to tissue formation
- Contributes to a reduction of tiredness and fatigue

Vitamin C:
- Contributes to iron absorption from food
- Helps to metabolise fats and proteins
- Helps in the development and maintenance of bones, cartilage, teeth and gums
- Contributes to cell protection from free radical damage
- Helps in connective tissue formation
- An antioxidant for the maintenance of good health

5.2 Pharmacokinetic properties
Pharmacokinetic studies have not been conducted on BIOGEN MAGNESIUM FIZZY. The vitamins and minerals in BIOGEN MAGNESIUM FIZZY are well absorbed from the gastrointestinal tract and are widely distributed to all tissues in the body.

5.3 Preclinical safety data
No pre-clinical safety data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium Bicarbonate, Citric Acid Anhydrous, Isomalt, Sorbitol, Tartaric Acid, Sucralose, Polyethylene glycol, Polyvinylpyrrolidone, Flavour and Colour.

6.2 Incompatibilities
Not applicable

6.3 Shelf Life
24 Months / 2 Years.

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 the container
Plastic tubes of 10 effervescent tablets, with a pink berry or vanilla flavour, 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
Biogen.
23 Stag Road,
Glen Austin,
South Africa.
Tel: 0860 347 243.
Email: info@biogen.co.za
Website: www.biogen.co.za

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION
Will be allocated by SAHPRA upon registration.