

**PROFESSIONAL INFORMATION**
**D 34.12 Multiple Substance Formulation. 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**  
**BIOGEN ZMA**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains		*%NRV
Magnesium (as Magnesium aspartate and Magnesium oxide)	93,24 mg	22
Zinc (as Zinc Mono-methionine)	6,28 mg	57
Pyridoxine (Vitamin B <sub>6</sub> ) (from Pyridoxine hydrochloride)	2,14 mg	127
Pantothenic Acid (Vitamin B <sub>5</sub> ) (from calcium D-pantothenate)	0,70 mg	14

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

Sugar Free

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Bovine gelatine capsules

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

BIOGEN ZMA, a combination of zinc, magnesium aspartate and vitamin B<sub>6</sub> to support the maintenance of normal muscle function and reduce tiredness and fatigue. Zinc contributes to the maintenance of normal testosterone levels in the blood. Magnesium contributes to the maintenance of normal muscle function & protein synthesis and Vitamin B<sub>6</sub> helps to promote normal red blood cell formation. Vitamin B<sub>5</sub> contributes to the reduction of tiredness and fatigue & normal mental performance.

**4.2 Posology and method of administration**

*Adults 18 years and older:*

Take 2 capsules daily, preferably on an empty stomach 30-60 minutes before bedtime, or as recommended by your healthcare provider. For optimal use, avoid taking with dairy or calcium-containing foods or supplements.

*Elderly:*

No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

*Patient with impaired renal and/or liver function:*

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

*Children and adolescents:*

Not recommended in children and adolescents below the age of 18 years (see section 4.4).

**4.3 Contraindications**

- If you have a hypersensitivity to Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>5</sub>, or any of the excipients listed in 6.1.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.

**4.4 Special warnings and precautions for use**

Special care should be taken with BIOGEN ZMA.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

**4.5 Interaction with other medicines and other forms of interaction**

- No specific drug interaction studies have been performed on BIOGEN ZMA, however, the pharmacokinetic properties of Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>5</sub> have been summarized.

**Interactions with Medicines**

- Magnesium can bind with certain medications, preventing their full absorption. If you are taking a tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), separate the time of the dose from the time of the magnesium supplement dose by at least 2 to 3 hours.
- If you are taking a bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), or a quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), ask your doctor or pharmacist about how long you should wait between doses and for help finding a dosing schedule that will work with all your medications.
- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Zinc and Amiloride can modestly reduce zinc excretion and increase zinc levels, decrease cephalixin levels by chelating with cephalixin in the gut and preventing its absorption.
- Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.
- Zinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5-1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.
- Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.
- Vitamin B<sub>6</sub> might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B<sub>6</sub> may reduce the levels and clinical effects of phenobarbital and phenytoin.

**Interactions with Diseases/Impairments**

- BIOGEN ZMA and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Supplemental vitamin B<sub>6</sub> at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.

**Interactions with Foods**

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing/ suggesting BIOGEN ZMA.
- Taking magnesium-containing supplements with food may reduce the risk of diarrhea.

**4.6 Fertility, pregnancy and lactation**

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN ZMA does not affect their performance.

**4.7 Undesirable effects**

Orally, Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>5</sub> is well-tolerated.

**Summary of adverse reactions**

Gastrointestinal disorders

*Less frequent:* constipation, flatulence, nausea, vomiting, heartburn, abdominal pain, mild diarrhea, and loss of appetite.

Nervous system disorders:

*Frequent:* headache, paresthesia, and somnolence.

Metabolism and nutrition disorders:

*Less frequent:* hypercalcaemia (particularly in patients with renal impairment or after high dosages), alkalosis.

Musculoskeletal:

*Frequency unknown:* breast soreness or enlargement.

**Description of selected adverse reactions**

BIOGEN ZMA may cause several adverse reactions, such as gastrointestinal disturbances, such as, digestive disorders, and constipation.

**Paediatric Population**

BIOGEN ZMA is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

**Other special populations**

Patients with Renal Impairment: Magnesium is contraindicated in patients with severe renal impairment (see Section 4.3). There is no dose adjustment necessary in patients with mild to moderate renal impairment. No clinical data are available on the effects of BIOGEN ZMA on other special populations.

**Reporting of side effects**

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>.

**4.8 Undesirable effects**

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**
**5.1 Pharmacodynamic properties**

D 34.1 Vitamins. Complementary Medicine: Health Supplement.

***Mechanism of action:***

Magnesium, is an essential cofactor for enzymes requiring ATP (these are involved in glycolysis, fatty acid oxidation and amino acid metabolism). It is also required for the synthesis of RNA and replication of DNA; neuromuscular transmission; and calcium metabolism.

Zinc, plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein. Zinc is also required for the hepatic synthesis of retinol-binding protein, the protein involved in transporting vitamin A.

Vitamin B<sub>6</sub>, required for amino acid metabolism. It is also involved in carbohydrate and lipid metabolism. In the body, vitamin B<sub>6</sub> is converted to the coenzyme pyridoxal phosphate for a wide variety of metabolic reactions. These reactions include transamination of amino acids, conversion of tryptophan to niacin, synthesis of gamma-aminobutyric acid (GABA) in the CNS, metabolism of serotonin, norepinephrine and dopamine, metabolism of polyunsaturated fatty acids and phospholipids, and the synthesis of the heme component of hemoglobin.

Vitamin B<sub>5</sub>, required in the acetylation reactions in gluconeogenesis; in the release of energy from carbohydrates; in the synthesis and degradation of fatty acids; and in the synthesis of sterols, steroid hormones, porphyrins, acetylcholine, and other compounds.

***Pharmacodynamic effects:***

Magnesium, is important for many biochemical processes and is therefore quite common in humans. The majority of magnesium is stored in the bones (>50%), while the remainder is stored in muscle, soft tissue, red blood cells and serum. This is functionally important since the bones behave as a magnesium exchange reservoir and help maintain healthy levels of magnesium.

Zinc, is required for the catalytic activity of more than 200 enzymes, and it plays a role in immune function wound healing, protein synthesis, DNA synthesis, and cell division.

Vitamin B<sub>6</sub>, supplementation might also be useful for some dysphoric mental states because it increases the production of serotonin and GABA.

Vitamin B<sub>5</sub>, required for intermediary metabolism of carbohydrates, proteins, and lipids. Dexpanthenol is converted in the body to pantothenic acid.

**5.2 Pharmacokinetic properties**

Absorption:

Magnesium, absorption of magnesium occurs principally in the jejunum and ileum by active carrier-mediated processes (partly dependent on vitamin D and parathyroid hormone) and by diffusion.

Zinc, Absorption occurs throughout the length of the small intestine, mostly in the jejunum, both by a carrier-mediated process and by diffusion.

Vitamin B<sub>6</sub>, is absorbed passively in the upper gastrointestinal tract.

Vitamin B<sub>5</sub>, Pantothenic acid is found in high levels in the brain when compared with the plasma, where it functions in normal biochemical pathways as the coenzyme, CoA. Acetyl-CoA, the precursor of acetylcholine, is derived from CoA. No clinical data are available on the effects of BIOGEN ZMA.

Distribution:

Magnesium, is widely distributed in the soft tissues and skeleton.

Zinc, is transported in association with albumin, amino acids and a 2-macroglobulin. Zinc is principally an intracellular ion and approximately 95% is found within the cells. Approximately 57% of the body pool is stored in skeletal muscle, 29% in bone and 6% in the skin, but zinc is found in all body tissues and fluids, including the liver, kidneys, pancreas, prostate gland and retina.

Vitamin B<sub>6</sub>, in the liver, vitamin B<sub>6</sub> is converted to the coenzyme pyridoxal phosphate.

Vitamin B<sub>5</sub>, No clinical data are available.

Metabolism:

Magnesium, does not appear to be metabolised.

Zinc, absorption of zinc is enhanced by certain amino acids such as cysteine and histidine: meat, dairy produce and fish contain these amino acids and therefore their zinc is efficiently absorbed.

Vitamin B<sub>5</sub>, No clinical data are available.

Excretion:

Magnesium, is largely via the urine (magnesium homeostasis is controlled mainly by the kidneys), with unabsorbed and endogenously secreted magnesium in the faeces. Small amounts are excreted in saliva and breast milk.

Zinc, Elimination of zinc is mainly in the faeces; smaller amounts are excreted in the urine and via the skin.

Vitamin B<sub>6</sub>, metabolites are excreted in the urine.

Vitamin B<sub>5</sub>, Pantothenic acid is excreted in the urine.

**5.3 Preclinical safety data**

When used orally and appropriately, Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>5</sub>, is recognized as possibly safe.

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**

Magnesium stearate and silicon dioxide.

**6.2 Shelf Life**

24 Months.

**6.3 Special precautions for storage**

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

60 capsules

The container is a 250 mL PET container. The cap is a plastic cap with a tamper evident seal.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Biogen

23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.

**10. DATE OF REVISION OF THE TEXT**

June 2022

<b>JOB:</b> BPS_ZMA 60s	<b>SIZE:</b> 210mm x 438mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b> <input checked="" type="checkbox"/> K <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot <input type="checkbox"/> Available Slot	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S0

**PRODUCT NAME**  
**BIOGEN ZMA**

Each capsule contains:  
Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>12</sub>.  
Sugar Free.

**D 34.12 Multiple Substance Formulation.**  
**Complementary Medicine: Health Supplement**

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

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

BIOGEN ZMA is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN ZMA carefully to get the best results from it.

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

**What is in this leaflet**

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

**1. What BIOGEN ZMA is and what it is used for**

BIOGEN ZMA, a combination of zinc, magnesium aspartate and vitamin B<sub>6</sub> to support the maintenance of normal muscle function and reduce tiredness and fatigue. Zinc contributes to the maintenance of normal testosterone levels in the blood. Magnesium contributes to the maintenance of normal muscle function & protein synthesis and Vitamin B<sub>6</sub> helps promote normal red blood cell formation. Vitamin B<sub>12</sub> contributes to the reduction of tiredness and fatigue & normal mental performance.

**2. What you need to know before you take BIOGEN ZMA**

**Do not take BIOGEN ZMA:**

- If you have a hypersensitivity Magnesium, Zinc, Vitamin B<sub>6</sub> and Vitamin B<sub>12</sub> or any of the excipients listed in 6.1.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.

**Warnings and precautions**

Special care should be taken with BIOGEN ZMA.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Not recommended for use in children under the age of 18 years.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

**Children and adolescents**

BIOGEN ZMA is not recommended for use in children under the age of 18 years.

**Other medicines and BIOGEN ZMA**

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine.

It is advised to consult your doctor if you want to take BIOGEN ZMA combined with other medicines or treatments such as:

- Magnesium can bind with certain medications, preventing their full absorption. If you are taking a tetracycline-type medication (such as demeclocycline, doxycycline, minocycline, tetracycline), separate the time of the dose from the time of the magnesium supplement dose by at least 2 to 3 hours.
- If you are taking a bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), or a quinolone-type antibiotic (e.g., ciprofloxacin, levofloxacin), ask your doctor or pharmacist about how long you should wait between doses and for help finding a dosing schedule that will work with all your medications.
- Concomitant use of aminoglycoside antibiotics and magnesium can increase the risk for neuromuscular weakness.
- Zinc and Amiloride can modestly reduce zinc excretion and increase zinc levels, decrease cephalaxin levels by chelating with cephalaxin in the gut and preventing its absorption.
- Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.
- Zinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5-1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.
- Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.
- Vitamin B<sub>6</sub> might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B<sub>6</sub> may reduce the levels and clinical effects of phenobarbital and phenytoin.

**Interactions with Diseases/Impairments**

- BIOGEN ZMA and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Supplemental vitamin B<sub>6</sub> at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.

**BIOGEN ZMA with food and drink**

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing/ suggesting BIOGEN ZMA.
- Taking magnesium-containing supplements with food may reduce the risk of diarrhea.

**Pregnancy, breastfeeding and fertility**

The safety and efficacy of BIOGEN ZMA in pregnancy and lactation has not been established.

**Driving and using machines**

Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN ZMA does not affect their performance.

**3. How to take BIOGEN ZMA**

Do not share your medicines with any other person.

Always take BIOGEN ZMA exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

*Adults 18 years and older:*

Take 2 capsules daily, preferably on an empty stomach 30-60 minutes before bedtime, or as recommended by your healthcare provider. For optimal use, avoid taking with dairy or calcium-containing foods or supplements.

*Elderly:*

No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

*Patient with impaired renal and/or liver function:*

In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4).

*Children and adolescents:*

Not recommended in children and adolescents below the age of 18 years (see section 4).

The safety and efficacy of BIOGEN ZMA in children has not yet been established. Not allowed in children under 18 years.

**If you take more BIOGEN ZMA than you should**

No known information. In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN ZMA with you so the doctor will know what you have taken.

**If you forget to take BIOGEN ZMA**

Do not take a double dose to make up for forgotten individual doses.

**4. Possible side effects**

BIOGEN ZMA can have side effects.

Not all side effects reported for BIOGEN ZMA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN ZMA, please consult your healthcare provider for advice.

Side effects associated;

*Less Frequent:*

Constipation, flatulence, nausea, vomiting, heartburn, abdominal pain, mild diarrhea, and loss of appetite.

*Frequent:*

Headache, paresthesia, and somnolence.

*Less frequent:*

Hypercalcaemia (particularly in patients with renal impairment or after high dosages), alkalosis.

*Frequency unknown:*

Breast soreness or enlargement.

Should your general health worsen or if you experience any untoward effects while BIOGEN ZMA, please consult your doctor, pharmacist or other healthcare practitioner for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction 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 BIOGEN ZMA.

**5. How to store BIOGEN ZMA**

Store at or below 25 °C.

Protect from light and moisture.

Store all medicines out of reach of children.

Do not use after the expiry date printed on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

**6. Contents of the pack and other information**

**What BIOGEN ZMA contains**

Active ingredients per capsule, Zinc, Magnesium, Vitamin B<sub>6</sub> and Vitamin B<sub>12</sub>.

Sugar Free.

The other ingredients are Magnesium stearate and Silicon dioxide.

**What BIOGEN ZMA looks like and contents of the pack**

60 Capsules

The container is a 250 mL PET container, with a Biogen embossed cap and a tamper evident seal.

**Holder of Certificate of Registration and Manufacturer**

Biogen

23 Stag Road, Glen Austin, South Africa

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Tel: 0860 347243

**This leaflet was last revised in**

June 2022

**Registration Number**

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD**

**SKEDULERINGSTATUS:** S0

**PRODUKNAAM**  
**BIOGEN ZMA**

Elke kapsule bevat:  
Sink, Magnesium, Vitamien B<sub>6</sub> en Vitamien B<sub>12</sub>.  
Suikervry.

**D 34.12 Meervoudige Bestanddeel Formulasie.**  
**Komplementêre Medisyne. Gesondheidsaanvulling.**

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

**Lees hierdie hele inligtingsblad aandagtig deur wat dit bevat inligting wat belangrik is vir u.**

BIOGEN ZMA is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN ZMA nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN ZMA met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteker indien u verdere inligting of advies nodig het.

**Wat is in hierdie inligtingsblad**

1. Wat is BIOGEN ZMA en waarvoor dit gebruik word.
2. Wat u moet weet voordat u BIOGEN ZMA neem.
3. Hoe om BIOGEN ZMA te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN ZMA te bêre.
6. Inhoud van die verpakking en ander inligting.

**1. Wat BIOGEN ZMA is en waarvoor dit gebruik word**

BIOGEN ZMA 'n kombinasie van sink, magnesiumaspartaat en vitamien B<sub>6</sub> om die handhawing van normale spierfunksie te ondersteun en moegheid en moegheid te verminder. Sink dra by tot die handhawing van normale testosteroonvlakke in die bloed. Magnesium dra by tot die handhawing van normale spierfunksie en proteïensintese en Vitamien B<sub>6</sub> help om normale rooibloedselvorming te bevorder. Vitamien B<sub>12</sub> dra by tot die vermindering van moegheid en moegheid en normale geestelike prestasie.

**2. Wat u moet weet voordat u BIOGEN ZMA neem**

**Moet nie BIOGEN ZMA neem nie:**

- As u 'n hipersensitiwiteit (allergie) het vir magnesium, sink, vitamien B<sub>6</sub> en vitamien B<sub>12</sub> of enige van die hulpstowwe wat in 6.1 gelys word.
- Word nie aanbeveel vir pasiënte wat bloedstillingsaanvullings gebruik nie, aangesien dit die risiko van spontane bloeding kan verhoog.

**Waarskuwings en voorsorgmaatreëls**

Spesiale sorg moet toegepas word met die gebruik van BIOGEN ZMA.

Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy swanger is of borsvoed.
- Nie aanbeveel vir gebruik by kinders onder die ouderdom van 18 jaar nie.
- Word nie aanbeveel vir pasiënte wat bloedstillingsaanvullings gebruik nie, aangesien dit die risiko van spontane bloeding kan verhoog.

Voedingsaanvulling behoort nie 'n gebalanseerde dieet te vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

**Kinders en adolessente**

BIOGEN ZMA word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

**Ander medisyne en BIOGEN ZMA**

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN ZMA wil kombineer saam met ander medisyne of behandeling soos:

- Magnesium kan met sekere medikasie bind, wat hul volle absorpsie verhoed. As jy 'n tetrasiklien-tipe medikasie (soos demeklosiklien, doksisisiklien, minosiklien, tetrasiklien) neem, skei die tyd van die dosis van die tyd van die magnesiumaanvullingsdosis met ten minste 2 tot 3 uur.
- As jy 'n bisfosonaat (byvoorbeeld alendronaat), 'n skildkliermedikasie (byvoorbeeld levotiroksien) of 'n kinoloon-tipe antibiotika (bv. siprofloksasien, levofloksasien) neem, vra jou dokter of apteker oor hoe lank jy moet wag tussen dosisse en vir hulp om 'n doseringskedule te vind wat met al jou medikasie sal werk.
- Gelyktydige gebruik van aminoglykosied antibiotika en magnesium kan die risiko vir neuromuskulêre swaakheid verhoog.
- Sink en Amiloride kan sink-uitskeiding beskeie verminder en sinkvlakke verhoog, kefaleksienvlakke verlaag deur chelaat met kefaleksien in die ingewande en die absorpsie daarvan te voorkom.
- Sink kan inmeng met die terapeutiese effekte van siprasidon, en die neem van sink saam met integrase-inhibeerdere kan die vlakke en kliniese effekte van hierdie medisyne verlaag.
- Sink meng in met penisillamien absorpsie en aktiwiteit. Sinkaanvullings verminder die doeltreffendheid van lae dosis penisillamien (0,5-1 gram/dag), maar dit lyk nie of dit hoër dosisse (1-2,75 gram/dag) beïnvloed nie, mits doseringstye geskei word. Pasiënte word aangeraai om sink en penisillamien ten minste 2 uur uitmekaar te neem.
- Kinolone vorm komplekse met sink in die spysverteringskanaal, wat absorpsie van beide die kinolone en sink verminder as dit gelyktydig geneem word. Pasiënte word aangeraai om hierdie middels ten minste 2 uur voor, of 4-6 uur na, sinkaanvullings te neem.
- Vitamien B<sub>6</sub> kan die fotosensitiwiteit wat deur amiodaron veroorsaak word, verhoog, additiewe effekte hê wanneer dit saam met antihypertensiewe middels gebruik word, kan die metabolisme van levodopa verhoog wanneer dit alleen geneem word, maar nie wanneer dit saam met karbidopa geneem word nie. Vitamien B<sub>6</sub> kan die vlakke en kliniese effekte van fenobarbital en fenitoin verminder.

**Interaksies met siektes**

- BIOGEN ZMA en gebruik by hemofilie en pasiënte wat vir chirurgie geskeduleer is, word aangeraai om die gebruik ten minste 2 weke voor elektiewe chirurgiese prosedures te staak (sien afdeling 4.4).
- Lae dieet-sinkname word geassosieer met 'n groter kans om chroniese nier siekte te ontwikkel.
- B-vitamiene kan die tempo van restenose verhoog na kaalmetaal stentplasing.
- Bariatriese chirurgie verminder sink absorpsie en kan sink ontoereikendheid veroorsaak ten spyte van sink aanvulling.
- Aanvullende vitamien B<sub>6</sub> op vlakke bo die dieetverwysingsinname (DRI) moet nie aanbeveel word na bariatriese chirurgie nie.

**BIOGEN ZMA met kos en drinkgoed**

- Vitamiene, minerale en voedingsstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer BIOGEN ZMA voorgeskryf/voorgestel word.
- Die neem van magnesiumbevattende aanvullings saam met kos kan die risiko van diarreë verminder.

**Swangerskap en borsvoeding**

Die veiligheid en doeltreffendheid van BIOGEN ZMA tydens swangerskap en laktasie is nie vasgestel nie.

**Bestuur en die gebruik van masjinerie**

Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat BIOGEN ZMA nie hul werkverrigting beïnvloed nie.

**3. Hoe om BIOGEN ZMA te neem**

Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN ZMA altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteker vir u aanbeveel het. Vra gerus u dokter of apteker indien u onseker is.

*Volwassenes 18 jaar en ouer:*

Neem 2 kapsules daaglik, verkieslik op 'n leë maag 30-60 minute voor slaaptid, of soos aanbeveel deur jou gesondheidsorgverskaffer. Vir optimale gebruik, vermy om saam met suiwel of kalsiumbevattende voedsel of aanvullings te neem.

*Bejaardes:*

Geen spesifieke studies is by ouer pasiënte uitgevoer nie, maar volgens kliniese ervaring is dosisaanpassing nie nodig wanneer andersins gesonde, ouer pasiënte behandel word nie.

*Pasiënt met verswakte nier- en/of lewerfunksie:*

By pasiënte met verswakte nier- en/of lewerfunksie kan geen dosisaanbevelings gegee word nie, aangesien geen studies uitgevoer is nie (sien ook afdeling 4).

*Kinders en adolessente:*

Word nie aanbeveel by kinders en adolessente onder die ouderdom van 18 jaar nie (sien afdeling 4).

Die veiligheid en doeltreffendheid van BIOGEN ZMA by kinders is nog nie vasgestel nie. Nie toegelaat by kinders onder 18 jaar nie.

**Wat om te doen indien u meer BIOGEN ZMA geneem het as wat u moet**

Geen bekende informasie. Indien u meer BIOGEN ZMA geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BIOGEN ZMA olie saam sodat die dokter kan sien wat u ingeneem het.

**Indien u vergeet om BIOGEN ZMA te neem**

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

**4. Moontlike nuwe-effekte**

BIOGEN ZMA kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir BIOGEN ZMA is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN ZMA, raadpleeg u gesondheidsorgwerker vir advies.

Nuwe-effekte geassosieer:

*Minder gereeld:*

Hardlywigheid, wonderigheid, naarheid, braking, soorbrand, buikpyn, ligte diarreë en verlies aan eetlus.

*Minder gereeld:*

Hiperkalsemie (veral by pasiënte met nierversaking of na hoë dosisse), alkalose.

*Dikwels:*

Hoofpyn, parestesie en slaperigheid.

*Frekwensie onbekend:*

Borseer of vergroting

Raadpleeg u dokter, apteker of ander gene -esheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN ZMA neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteker daarvan in kennis gestel word.

**Rapportering van nuwe-effekte**

Praat met u dokter of apteker as u nuwe-effekte kry. 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 te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN ZMA te verskaf.

**5. Hoe om BIOGEN ZMA te stoor**

Bêre by of onder 25 °C.

Beskerm teen lig en vog.

Bêre alle medisyne buite bereik van kinders.

Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.

Neem alle ongebruikte medisyne terug na u apteker.

Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

**6. Inhoud van die verpakking en ander inligting**

**Wat BIOGEN ZMA bevat:**

Aktiewe bestanddele per kapsule Sink, Magnesium, Vitam