



CALMAG MAX

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 CALMAG MAX

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains		%NRV*
Calcium carbonate (providing 600,00 mg elemental Calcium)	1 667,00 mg	46 %
Magnesium oxide (providing 125,00 mg elemental Magnesium)	207,30 mg	30 %
Zinc oxide (providing 12,50 mg elemental Zinc)	15,60 mg	114 %
Boron chelate (providing 1,50 mg elemental Boron)	35,00 mg	
Copper sulphate pentahydrate (providing 2,00 mg elemental Copper)	8,00 mg	222 %
Manganese sulphate monohydrate (providing 2,00 mg elemental Manganese)	6,20 mg	87 %
K2VITAL® Delta (Providing 45,00 µg All-trans micro-encapsulated Vitamin K2 MK-7)	22,50 mg 45,00 µg	38 %
Cholecalciferol (Vitamin D ₃)	500,00 IU (12,50 µg)	83 %

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

Contains sucrose, 9,9 mg per tablet.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN CALMAG MAX, a multi-mineral supplement that helps maintain healthy calcium metabolism and contributes to the development and maintenance of strong bones and healthy teeth. A factor in the maintenance of good health.

4.2 Posology and method of administration

Adults:
Take 1-2 (one to two) tablets daily, with food or as recommended by your healthcare provider.

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.

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 the ingredients or any of the excipients listed in 6.1.
- Calcium are contraindicated in patients with ventricular fibrillation or hypercalcaemia.
- Copper, as in BIOGEN CALMAG MAX should not be used in Wilson's disease (the disorder may be exacerbated); or hepatic and biliary disease.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN CALMAG MAX.
If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.
Please take note of the following:

- Calcium should be used cautiously, if at all, in patients with sarcoidosis, renal or cardiac disease, and in patients receiving cardiac glycosides.
- The presence of another joint disease and alternative treatment thereof should be excluded.
- No special studies were performed in patients with renal or hepatic insufficiency. The toxicological and pharmacokinetic profile of the product does not indicate limitations for these patients. However, administration to patients with severe hepatic or renal insufficiency should be under medical supervision.

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 CALMAG MAX, however, the pharmacokinetic properties of Calcium, Magnesium, Zinc, Boron, Copper, Manganese, Vitamin K₂ and Vitamin D₃ have been summarized.

Interactions with Medicines

- Calcium carbonate interacts with many other medicines both by alterations in gastric pH and emptying, and by formation of complexes that are not absorbed. Interactions can be minimised by giving calcium carbonate and any other medicine 2 to 3 hours apart.
- Calcium concentrations in the plasma should therefore be monitored in such situations.
- Concomitant administration of calcium with bisphosphonates (e.g., Alendronate, Etidronate, Ibandronate, Risedronate) may reduce absorption of the bisphosphonate from the gastrointestinal tract. To minimize this effect, the drugs should be administered at separate times.
- Concomitant administration of calcium and oral iron preparations may result in reduced absorption of iron. Patients should be advised to take the drugs at different times, whenever possible.
- Calcium carbonate may form an insoluble chelate with levothyroxine, resulting in decreased levothyroxine absorption and increased serum thyrotropin concentrations. To minimize or prevent this interaction, oral levothyroxine sodium should be administered at least 4 hours apart from calcium carbonate, as in BIOGEN CALMAG MAX.
- Concomitant administration of calcium and some Fluoroquinolones (e.g., Ciprofloxacin) may reduce oral bioavailability of the Fluoroquinolone. Patients are advised to discuss timing of drug administration when concomitant use is necessary.
- Concomitant administration of calcium and magnesium salts decreases the absorption of Tetracyclines and bisphosphonates, and doses should be separated by a number of hours.
- Certain nutrients such as calcium can bind to antibiotics in the stomach and reduce their absorption and effectiveness. Depending on the antibiotic prescribed, you may need to separate taking any calcium containing supplements from antibiotics by at least 2 to possibly 6 hours or discontinue your dietary supplement while taking the antibiotic.
- Patients are advised to not concomitantly administer Cardiac Glycosides and calcium due to synergistic effects and arrhythmias may occur if these drugs are given together.
- Vitamin K₂ decreases the effects of oral anticoagulants and is used to counteract excessive effects of these medicines.
- Thiazide diuretics may increase the risk of hypercalcaemia when used in combination with vitamin D.
- Penicillamine and Trientine may reduce absorption of copper and vice versa, patients are advised to administer 2 hours apart from taking BIOGEN CALMAG MAX.

Interactions with Diseases/Impairments

- BIOGEN CALMAG MAX and use in Haemophilacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- Copper toxicity may also occur in patients with Wilson's disease (an inherited disorder in which patients exhibit a deficiency of plasma caeruloplasmin and an excess of copper in the liver and bloodstream).

Interactions with Foods

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

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Orally, Calcium, Magnesium, Zinc, Boron, Copper, Manganese, Vitamin K₂, and Vitamin D₃ is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Less frequent: Constipation and flatulence.

Metabolism and nutrition disorders:

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

Description of selected adverse reactions

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

Paediatric Population

BIOGEN CALMAG MAX 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 CALMAG MAX on other special populations.

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. 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/6>.

4.9 Overdose

See section 4.8.
In the event of overdose, treatment should be symptomatic and supportive.

Calcium carbonate: Gastric hypersecretion, acid rebound or hypercalcaemia may occur when calcium carbonate is taken at high doses or with prolonged use.

Vitamin K₂: Side effects which have been reported after overdose include jaundice, hyperbilirubinaemia, increases in liver enzyme values, abdominal pain, constipation, soft stools, malaise, agitation and skin eruptions. Most adverse events were not considered to be serious and resolved without any treatment.

Vitamin D₃: Excessive intake of vitamin D leads to the development of hyperphosphataemia or hypercalcaemia (including hypercalciuria, ectopic calcification, and renal and cardiovascular damage). Symptoms of overdosage include anorexia, lassitude, nausea and vomiting, constipation or diarrhoea, polyuria, nocturia, sweating, headache, thirst, somnolence and vertigo.

5. PHARMACOLOGICAL PROPERTIES

BIOGEN CALMAG MAX, a multi-mineral supplement that helps maintain healthy calcium metabolism and contributes to the development and maintenance of strong bones and healthy teeth. A factor in the maintenance of good health.

5.1 Pharmacodynamic properties

Mechanism of action:

Calcium is essential for maintenance of the functional integrity of nervous, muscular, and skeletal systems and cell membrane and capillary permeability. Calcium also plays regulatory roles in the release and storage of neurotransmitters and hormones, in the uptake and binding of amino acids, and in cyanocobalamin (vitamin B₁₂) absorption and gastrin secretion.

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.

Boron, is important in calcium metabolism, and can affect the composition, structure and strength of bone. It may also influence the metabolism of copper, magnesium, phosphorus, potassium and vitamin D.

Copper, plays a role in bone formation and mineralisation.

Manganese activates several enzymes, including hydroxylases, kinases, decarboxylases and transferases. It may have a role in the regulation of glucose homeostasis and in calcium mobilisation.

Vitamin K may increase bone formation by regulating the transcription of osteoblast markers involved in bone format.

Vitamin D₃ for the maintenance of normal levels of serum calcium and phosphorus in the bloodstream by enhancing the efficacy of the small intestine to absorb these minerals from the diet.

Pharmacodynamic effects:

Calcium, plays a role in the physiology and biochemistry of organisms and the cell, extracellular calcium is important for maintaining the potential difference across excitable cell membranes, as well as proper bone formation.

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.

Boron, plays an important role in osteogenesis, and its deficiency has been shown to adversely impact bone development and regeneration. Boron influences the production and activity of steroid hormones, actions via which this trace mineral is involved in the prevention of calcium loss and bone demineralization.

Copper is incorporated into many enzymes throughout the body as an essential part of their function.

Manganese an essential nutrient that acts as a cofactor in several metabolic and enzymatic reactions. Manganese might have a role in osteoporosis. Decreased plasma manganese concentrations have been linked to osteoporosis, and bone mineral density seems to improve when trace minerals including manganese are added to calcium supplementation.

Vitamin K₂, a cofactor for carboxylation of matrix Gla proteins, including osteocalcin, in bone and cartilage.

Vitamin D₃: main function of vitamin D is to regulate serum calcium and phosphorus concentrations. Vitamin D enhances the efficiency of the intestinal absorption of calcium, primarily in the duodenum and jejunum, and phosphorus, particularly in the jejunum and ilium. Vitamin D is important for calcium homeostasis and for bone health, it is used to help prevent osteoporosis.

5.2 Pharmacokinetic properties

Absorption:

Calcium is absorbed from the GI tract by active transport and passive diffusion. Calcium is actively absorbed in the duodenum and proximal jejunum and, to a lesser extent, in the more distal segments of the small intestine.

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.

Boron is absorbed through the intestinal epithelia, and across mucous tissues, such as the eyes, mouth, and urinary system.

Copper is absorbed mainly in the small intestine, with a small amount absorbed in the stomach.

Manganese absorption occurs throughout the length of the small intestine, probably via a saturable carrier mechanism, but absorptive efficiency is believed to be poor.

Vitamin K₂ (menaquinone) are well absorbed, with peak blood levels occurring 4 hours after intake. Menaquinones MK-7 through MK-10 are synthesized by bacteria in the colon.

Vitamin D₃ is readily absorbed from the small intestine if fat absorption is normal.

No clinical data are available on the effects of BIOGEN CALMAG MAX.

Distribution:

Following absorption, calcium first enters the extracellular fluid and is then rapidly incorporated into skeletal tissue. Bone formation, however, is not stimulated by administration of calcium. Bone contains 99% of the body's calcium; the remaining 1% is distributed equally between the intracellular and extracellular fluids.

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.

Boron is distributed throughout the body tissues; the highest concentrations are found in the bone, teeth, fingernails, spleen and thyroid.

Copper is rapidly taken up by the liver and incorporated into caeruloplasmin. It is stored primarily in the liver. Copper is transported bound to caeruloplasmin.

Manganese is transported in the blood bound to plasma proteins. Organs with the highest concentrations include the liver, kidney and pancreas, but 25 % of the body pool is found within the skeleton. Homeostasis is maintained by hepatobiliary and intestinal secretion.

Vitamin K₂, are transported with both low-density lipoprotein (LDL)- and triacylglycerol-rich fractions of plasma lipoproteins, reaching the liver and many extrahepatic tissues.

Vitamin D is transported primarily by chylomicron, which allows vitamin D to be distributed to peripheral tissues. If not taken up by peripheral tissue, vitamin D is transported to the liver, where it is converted to calcitriol.

Metabolism:

Vitamin D, in its activated forms, is required for calcium metabolism and increases the capability of the absorptive mechanisms. Active transport of calcium into enterocytes and out on the serosal side of the intestinal mucosa depends on the action of activated vitamin D (1,25-dihydroxyvitamin D) and its intestinal receptors; this mechanism accounts for most of the calcium absorption from the GI tract at low and moderate intake levels.

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

Boron is metabolised by a saturable carrier-mediated mechanism at low levels of intake, and by passive diffusion at high levels of intake.

Copper is reduced to the Cu1+ form prior to transport. Once inside the enterocyte, it is bound to copper transport protein ATOX1 which shuttles the ion to copper transporting ATPase-1 on the golgi membrane which take up copper into the golgi apparatus.

Manganese is bound to transmanganin, a beta-1-globulin. Manganese is stored in the brain, kidneys, pancreas, and liver.

Vitamin K₂ is metabolised by the pancreas, testes, and arterial vessel walls.

Vitamin D₃; within the liver, cholecalciferol is hydroxylated to calcifediol (25-hydroxycholecalciferol) by the enzyme vitamin D-25-hydroxylase 12,13,14. At the kidney, calcifediol subsequently serves as a substrate for 1-alpha-hydroxylase, yielding calcitriol (1,25-dihydroxycholecalciferol), the biologically active form of vitamin D₃.

Excretion:

Calcium is excreted mainly in the feces and consists of unabsorbed calcium and that secreted via bile and pancreatic juice into the lumen of the GI tract. Most of the calcium filtered by renal glomeruli is reabsorbed in the ascending limb of the loop of Henle and proximal and distal convoluted tubules. Only small amounts of the cation are excreted in urine.

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.

Boron is mainly excreted in the urine.

Copper: Once copper has been secreted by enterocytes into the systemic circulation it remain largely bound by ceruloplasmin (65-90 %), albumin (18 %), and alpha 2-macroglobulin (12 %), it is excreted mainly via bile into the faeces; small amounts are excreted in the urine, sweat and via epidermal shedding.

Manganese is eliminated primarily in the faeces.

Vitamin K₂ are excreted in both urine and feces and the form and route of excretion may depend on the amount in the diet.

Vitamin D₃; administered cholecalciferol and its metabolites are excreted primarily in the bile and feces.

Preclinical safety data

When used orally and appropriately, Calcium, Magnesium, Zinc, Boron, Copper, Manganese, Vitamin K₂ and Vitamin D₃ is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, 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

30 / 60 / 120 White oval tablets
The container is a 175 mL / 250 mL / 300 mL PET container. The cap is a white 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

November 2021

JOB: BPS_Calmag Max 30,60, 120s		SIZE: 210mm x 397mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
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<input type="checkbox"/> Spot UV		<input type="checkbox"/> Doming	<input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY 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 CALMAG MAX

Each tablet contains:
Calcium, Magnesium, Zinc, Boron, Copper, Manganese, Vitamin K₂ and Vitamin D₃.
Contains sucrose, 9,9 mg per tablet.

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.

Read all of this leaflet carefully because it contains important information for you.
BIOGEN CALMAG MAX is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN CALMAG MAX carefully to get the best results from it.

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

1. What BIOGEN CALMAG MAX is and what it is used for
BIOGEN CALMAG MAX a multi-mineral supplement that helps maintain healthy calcium metabolism and contributes to the development and maintenance of strong bones and healthy teeth. A factor in the maintenance of good health.

2. What you need to know before you take BIOGEN CALMAG MAX
Do not take BIOGEN CALMAG MAX:

- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.
- Calcium are contraindicated in patients with ventricular fibrillation or hypercalcaemia.
- Copper, as in BIOGEN CALMAG MAX should not be used in Wilson's disease (the disorder may be exacerbated); or hepatic and biliary disease.

Warnings and precautions
Special care should be taken with BIOGEN CALMAG MAX.
If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Calcium should be used cautiously, if at all, in patients with sarcoidosis, renal or cardiac disease, and in patients receiving cardiac glycosides.
- The presence of another joint disease and alternative treatment thereof should be excluded.
- No special studies were performed in patients with renal or hepatic insufficiency. The toxicological and pharmacokinetic profile of the product does not indicate limitations for these patients. However, administration to patients with severe hepatic or renal insufficiency should be under medical supervision.

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

Children and adolescents
BIOGEN CALMAG MAX is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN CALMAG MAX
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 CALMAG MAX combined with other medicines or treatments such as:

- Calcium carbonate interacts with many other medicines both by alterations in gastric pH and emptying, and by formation of complexes that are not absorbed. Interactions can be minimised by giving calcium carbonate and any other medicine 2 to 3 hours apart.
- Calcium with bisphosphonates (e.g., Alendronate, Etidronate, Ibandronate, Risedronate) may reduce absorption of the bisphosphonate from the gastrointestinal tract. Take at least 2 to 4 hours apart.
- Calcium and oral iron preparations may result in reduced absorption of iron. It is advised to take the drugs at different times, whenever possible.
- Levothyroxine sodium may cause interactions and should be administered at least 4 hours apart from calcium carbonate, as in BIOGEN CALMAG MAX.
- Calcium and some Fluoroquinolones (e.g., Ciprofloxacin) may reduce oral bioavailability of the Fluoroquinolone. It is advised to discuss timing of drug administration when concomitant use is necessary.
- Calcium and magnesium salts decreases the absorption of Tetracyclines and bisphosphonates, and doses should be separated by a number of hours.
- It is advised to take BIOGEN CALMAG MAX and antibiotics separately by at least 2 to possibly 6 hours or discontinue BIOGEN CALMAG MAX while taking the antibiotic.
- Cardiac Glycosides and calcium, as in BIOGEN CALMAG MAX may cause interactions due to synergistic effects. Arrhythmias may occur if taken together.
- Vitamin K₂ decreases the effects of oral anticoagulants and is used to counteract excessive effects of these medicines.
- Thiazide diuretics may increase the risk of hypercalcaemia when used in combination with vitamin D.
- Penicillamine and Tientine may reduce absorption of copper and vice versa, it is advised to administer 2 hours apart from taking BIOGEN CALMAG MAX.

Interactions with Diseases / Impairments

- BIOGEN CALMAG MAX 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).
- Copper toxicity may also occur in patients with Wilson's disease (an inherited disorder in which patients exhibit a deficiency of plasma caeruloplasmin and an excess of copper in the liver and bloodstream).

Interactions with Foods
Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN CALMAG MAX.

Pregnancy, breastfeeding and fertility
The safety and efficacy of BIOGEN CALMAG MAX in pregnancy and lactation has not been established.

Driving and using machinery
Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN CALMAG MAX does not affect their performance.

3. ow to take BIOGEN CALMAG MAX
Do not share your medicines with any other person.

Always take BIOGEN CALMAG MAX 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:
Take 1 - 2 (one to two) tablets daily, with food or as recommended by your healthcare provider.

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 CALMAG MAX in children has not yet been established. Not allowed in children under 18 years.

If you take more BIOGEN CALMAG MAX than you should
No known information. In the event of an overdosage, 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 CALMAG MAX with you so the doctor will know what you have taken.

If you forget to take BIOGEN CALMAG MAX
Do not take a double dose to make up for forgotten individual doses.

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

Side effects associated;
Less Frequent: Constipation and flatulence.
Less Frequent: Hypercalcaemia (particularly in patients with renal impairment or after high dosages), alkalosis.
Should your general health worsen or if you experience any untoward effects while BIOGEN CALMAG MAX, 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 side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 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 BIOGEN CALMAG MAX.

5. How to store BIOGEN CALMAG MAX

- 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 CALMAG MAX contains
Active ingredients per tablet Calcium, Magnesium, Zinc, Boron, Copper, Manganese, Vitamin K₂ and Vitamin D₃.
Contains sucrose, 9,9 mg per tablet
The other ingredients are Microcrystalline cellulose, Magnesium stearate and Silicon dioxide.

What BIOGEN CALMAG MAX looks like and contents of the pack
30 / 60 / 120 White oval tablets
The container is a 175 mL / 250 mL / 300 mL PET container. The cap is a white plastic cap with a tamper evident seal.

Holder of certificate of registration
Biogen
23 Stag Road, Glen Austin, South Africa
info@biogen.co.za
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Tel: 0860 347243

This leaflet was last revised in
November 2021.

Registration Number
Will be allocated by SAHPRA upon registration.

PASIÉNTINLIGTINGSBLAD

SKEDULERINGSTATUS: **[S0]**

PRODUKNAAM
BIOGEN CALMAG MAX

Elke tablet bevat:
Kalsium, Magnesium, Sink, Boron, Koper, Mangaan, Vitamien K2 en Vitamien D₃.
Bevat suikrose, 9,9 mg per tablet.

D 34.12 Meervoudige Bestanddeel Formulasie. Komplementêre Medisyne. Gesondheidsaanvulling.
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.
Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN CALMAG MAX is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN CALMAG MAX nietiemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN CALMAG MAX 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 CALMAG MAX en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN CALMAG MAX neem.
3. Hoe om BIOGEN CALMAG MAX te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN CALMAG MAX te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIOGEN CALMAG MAX en waarvoor word dit gebruik
BIOGEN CALMAG MAX 'n veelvuldige-minerale aanvulling wat help om gesonde kalsiummetabolisme te handhaaf en dra by tot die ontwikkeling en instandhouding van sterk bene en gesonde tande. 'n Faktor in die handhawing van goeie gesondheid.

2. Wat u moet weet voordat u BIOGEN CALMAG MAX neem
Moenie BIOGEN CALMAG MAX neem nie:

- Indien u hipersensitief (allergies) is vir enige van die ander bestanddele gelys (sien afdeling 6).
- Indien u gediagnoseer is met ventrikulêre fibrillasie of hiperkalsemie.
- Indien u Wilson se siekte het (die afwyking kan vererger word); of lewer- en galsiekte.

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet toegepas word met die gebruik van BIOGEN CALMAG MAX .
Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- Kalsium moet versigtig gebruik word, indien enigsins, indien u met sarkoidose, nier- of hartsiekte, gediagnoseer is en indien u hartglykosiede ontvang.
- Die teenwoordigheid van 'n ander gewrigsiekte en alternatiewe behandeling daarvan moet uitgesluit word.
- Geen spesiale studies is uitgevoer in pasiënte met nier- of lewerversaking nie. Die toksikologiese en farmakokinetiese profiel van die produk dui nie op beperkings vir hierdie pasiënte nie. Toediening indien u ernstige lewer- of nierinsuffisientie het moet egter onder mediese toesig wees.Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie.

Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente
BIOGEN CALMAG MAX word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

Ander medisyne en BIOGEN CALMAG MAX
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 CALMAG MAX wil kombineer saam met ander medisyne of behandelinge soos:

- Kalsiumkarbonaat is in wisselwerking met baie ander medisyne, beide deur veranderinge in maag pH en leegmaak, en deur die vorming van komplekse wat nie geabsorbeer word nie. Interaksies kan tot die minimum beperk word deur kalsiumkarbonaat en enige ander medisyne 2 tot 3 uur uitmekaar te gee.
- Kalsium met bisfosfonate (bv. Alendronaat, Etidronaat, Ibandronaat, Risedronaat) kan absorpsie van die bisfosfonaat uit die spysverteringskanaal verminder. Neem ten minste 2 tot 4 uur uitmekaar.
- Kalsium en orale ysterpreparate kan lei tot verminderde absorpsie van yster. Dit word aanbeveel om die middels op verskillende tye te neem, waar moontlik.
- Levotiroksiennatrium kan interaksies veroorsaak en moet ten minste 4 uur apart van kalsiumkarbonaat toegedien word, soos in BIOGEN CALMAG MAX.
- Kalsium en sommige Fluorokinolone (bv. Ciprofloxacin) kan orale biobeskikbaarheid van die Fluorokinolone verminder. Dit word aangeraai om tydskerekening toediening met u gesondheidsorgverskaffer te bespreek wanneer geklytdig gebruik nodig is.
- Kalsium- en magnesiumsoute verminder die absorpsie van tetrasiklene en bisfosfonate, en dosisse moet met 'n aantal ure geskei word.
- Dit word aanbeveel om BIOGEN CALMAG MAX en antibiotika afsonderlik te neem met ten minste 2 tot moontlik 6 uur of om BIOGEN CALMAG MAX te staak terwyl die antibiotika geneem word.
- Kardiale Glykosiede en kalsium, soos in BIOGEN CALMAG MAX, kan interaksies veroorsaak as gevolg van sinergistiese effekte. Aritmieë kan voorkom as dit saam geneem word.
- Vitamien K₂ verminder die uitwerking van orale antikoagulanste en word gebruik om oormatige effekte van hierdie medisyne teë te werk.
- Tiasieddiuretika kan die risiko van hiperkalsemie verhoog wanneer dit in kombinasie met vitamien D gebruik word.
- Penisillamien en Tientrine kan absorpsie van koper verminder en omgekeerd, dit word aangeraai om 2 ure apart van die neem van BIOGEN CALMAG MAX toe te dien.

Interaksies met siektes / gestremdhede

- BIOGEN CALMAG MAX 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).
- Kopertoksiteit kan ook voorkom by pasiënte met Wilson se siekte ('n oorerflike afwyking waarin pasiënte 'n tekort aan plasma caeruloplasmin en 'n oormaat koper in die lewer en bloedstroom toon).

Interaksies met voedsel
Vitamiene, minerale en voedingstowwe wat van ander bronne verkry word, moet in ag geneem word wanneer BIOGEN CALMAG MAX voorgeskryf / voorgestel word.

Swangerskap, borsvoeding en vrugbaarheid
Die veiligheid en doeltreffendheid van BIOGEN CALMAG MAX tydens swangerskap en laktasie is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat BIOGEN CALMAG MAX nie hul werkverrigting beïnvloed nie.

3. Hoe om BIOGEN CALMAG MAX te neem
Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN CALMAG MAX 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:
Neem 1-2 (een tot twee) tablette daaglik, of soos aanbeveel deur jou gesondheidsorgverskaffer.
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 CALMAG MAX by kinders is nog nie vasgestel nie. Nie toegelaat by kinders onder 18 jaar nie.

Wat om te doen indien u meer BIOGEN CALMAG MAX geneem het as wat u moet
Geen bekende informasie. Indien u meer BIOGEN CALMAG MAX 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 CALMAG MAX olie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN CALMAG MAX te neem
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike nuwe-effekte
BIOGEN CALMAG MAX kan nuwe-effekte hê.
Nie alle nuwe-effekte wat aangemeld is vir BIOGEN CALMAG MAX is in hierdie vouiljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN CALMAG MAX, raadpleeg u gesondheidsorgwerker vir advies.

Nuwe-effekte geassosieer:
Minder gereeld: Hardlywigheid en winderigheid.
Minder gereeld: Hiperkalsemie (veral by pasiënte met nierversaking of na hoë dosisse), alkalose.
Raadpleeg u dokter, apteker of ander gene-esheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN CALMAG MAX 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
Indien u nuwe-effekte ondervind, bespreek dit met u dokter of apteker. U kan ook nuwe-effekte aan SAHPRA rapporteer via die Adverse Drug Reactions Reporting Form, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.
Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN CALMAG MAX te verskaf.

5. Hoe om BIOGEN CALMAG MAX te bêre

- 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 pak en ander inligting

Wat BIOGEN CALMAG MAX bevat
Aktiewe bestanddele per tablet, Kalsium, Magnesium, Sink, Boron, Koper, Mangaan, Vitamien K₂, en Vitamien D₃.
Bevat suikrose, 9,9 mg per tablet.
Die ander bestanddele is Mikrokrystallose sellulose, Magnesiumsteraat, en Silikondioksien.

Hoe BIOGEN CALMAG MAX lyk en inhoud van die verpakking
30 / 60 / 120 Wit ovaal tablette
Die verpakking is 'n 175 mL / 250 mL / 300 mL PET houer met 'n Biogen deksel.

Houer van die registrasiesertifikaat
Biogen
Stagweg 23, Glen Austin, Suid Afrika
info@biogen.co.za
www.biogen.co.za
Tel: 0860 347243

Hierdie inligtingsblad is laas hersien in
November 2021.

REGISTRASIENOMMER
Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_Calmag Max 30,60, 120s		SIZE: 210mm x 397mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<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
<input type="checkbox"/> Spot UV		<input type="checkbox"/> Doming	
<input type="checkbox"/> Embossing			
PLEASE CHECK CAREFULLY			
Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			