

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### BONE BUILDER WITH MAGNESIUM,

#### 90 Tablets

#### COMPOSITION

Each one (1) tablet of BONE BUILDER WITH MAGNESIUM contain the following actives:

Calcium (as Microcrystalline Hydroxyapatite Concentrate and Dicalcium phosphate)	206 mg
Phosphorus (as Microcrystalline Hydroxyapatite Concentrate and Dicalcium phosphate)	116 mg
Magnesium (as Magnesium citrate, Magnesium aspartate and Magnesium bis-glycinate)	100 mg
Vitamin D (as Cholecalciferol)	5 µg (200 I.U.)

**Inactive Ingredients** : Cellulose, hydroxypropyl cellulose, hypromellose, medium chain triglycerides, silica, sodium starch glycolate, stearic acid.

**This product is gluten free and non-GMO (Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

**BONE BUILDER WITH MAGNESIUM** is designed to support bone mineral density and also features vitamin D and magnesium for enhanced bone support and healthy muscle function.

Ingredients	Uses for ingredient
Calcium (as Microcrystalline Hydroxyapatite Concentrate and Dicalcium phosphate)	Hydroxyapatite is a calcium-phosphate mineral complex that provides bone and teeth with their structural hardness and integrity.
Phosphorus (as Microcrystalline Hydroxyapatite Concentrate and Dicalcium phosphate)	It plays a role in the structural strength of bone and in bone regeneration.
Magnesium (as Magnesium citrate, Magnesium aspartate and Magnesium bis-glycinate)	Magnesium citrate is a form of magnesium that's bound with citric acid. This type is among the most bioavailable forms of magnesium, meaning it's more easily absorbed in your digestive tract than other forms.
Vitamin D (as Cholecalciferol)	Cholecalciferol is needed by the body for healthy bones, muscles, nerves, and to support the immune system. It works by helping the body to use more of the calcium found in foods or supplements.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **BONE BUILDER WITH MAGNESIUM** if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. Taking antibiotics along with **BONE BUILDER WITH MAGNESIUM** can reduce the effects of the medicine. To avoid this interaction, take **BONE BUILDER WITH MAGNESIUM** at least 2 hours before or after antibiotics.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: high calcium levels (hypercalcemia), kidney disease (including kidney stones), little or no stomach acid (achlorhydria), heart disease, disease of the pancreas, a certain lung disease (sarcoidosis), difficulty absorbing nutrition from food (malabsorption syndrome), diabetes, bleeding disorders, heart block. If you are taking the following medication, please consult with your healthcare professional before taking: digoxin, cellulose sodium phosphate, certain phosphate binders (such as calcium acetate), anticoagulants (Warfarin), diabetic medication, blood pressure medication. If any of the following happens, stop using **BONE BUILDER WITH MAGNESIUM** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;
- Nausea/vomiting, loss of appetite, unusual weight loss, mental/mood changes, bone/muscle pain, headache, increased thirst/urination, weakness, unusual tiredness.



These are all very serious effects. If you have them, you may have had a serious reaction to **BONE BUILDER WITH MAGNESIUM**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Gastrointestinal discomfort: Bloating, gas, or constipation.
- These are all very serious effects. If you have them, you may have had a serious reaction to **BONE BUILDER WITH MAGNESIUM**. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

**DO NOT USE THIS PRODUCT:**

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

#### INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

#### DOSAGE AND DIRECTIONS FOR USE

**Adults:** Take one (1) tablet daily with food or as directed by your healthcare practitioner.

**Do not take more than the recommended dose.**

#### SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

#### KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

**Treatment:**

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

#### STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use **BONE BUILDER WITH MAGNESIUM** if you notice visible signs of deterioration.

#### IDENTIFICATION

White, oblong coated tablet.

#### PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

#### NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:  
Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146  
Tel: 011-802-8101

#### DATE OF PUBLICATION

To be allocated by the regulatory authority.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

## BONE BUILDER WITH MAGNESIUM,

### 90 Tablette

#### SAMESTELING

Elke (1) tablet BONE BUILDER WITH MAGNESIUM bevat die volgende

aktiewe stowwe:

Kalsium (as Mikrokristallyn Hidroksiapatiet-Konsentraat en Dikalsiumfosfaat)	206 mg
Fosfor (as Mikrokristallyne Hidroksiapatiet-Konsentraat en Dikalsiumfosfaat)	116 mg
Magnesium (as Magnesiumsitraat, Magnesium aspartaat en Magnesium bisglisinaat)	100 mg
Vitamiën D (as Cholekalsiferol)	5 µg (200 IE)

**Onaktiewe bestanddele:** Sellulose, hidroksiopropielsellulose, hipomellose, mediumkettig trigliseriede, silika, natriumstyselglikolaat, steariensuur.

**Hierdie produk is glutenvry en nie-GGO (Suikervry)**

#### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

#### AANDUIDING EN FARMAKOLOGIESE WERKING

**BONE BUILDER WITH MAGNESIUM** is ontwerp om beenmineraaldigtheid te ondersteun en beskik oor vitamien D en magnesium vir verbeterde beenondersteuning en gesonde spierfunksie.

Bestanddele	Gebruike vir bestanddeel
Kalsium (as mikrokristallyne hidroksiapatietkonsentraat en dikalsiumfosfaat)	Hydroxyapatite is 'n kalsium-fosfaat minerale kompleks wat been en tande met hul strukturele hardheid en integriteit voorsien.
Fosfor (as mikrokristallyne hidroksiapatietkonsentraat en dikalsiumfosfaat)	Dit speel 'n rol in die strukturele sterkte van been en in beenregenerasie.
Magnesium (as magnesiumsitraat, magnesiumaspartaat en magnesiumbis-glycinaat)	Magnesiumsitraat is 'n vorm van magnesium wat met sietroensuur gebind is. Hierdie tipe is een van die mees bio-beskikbare vorme van magnesium, wat beteken dat dit makliker in jou spysverteringskanaal geabsorbeer word as ander vorme.
Vitamiën D (as Cholekalsiferol)	Cholekalsiferol word deur die liggaam benodig vir gesonde bene, spiere, senuwees en om die immuunstelsel te ondersteun. Dit werk deur die liggaam te help om meer van die kalsium wat in voedsel of aanvullings voorkom, te gebruik.

#### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **BONE BUILDER WITH MAGNESIUM** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem. Die neem van antibiotika saam met **BONE BUILDER WITH MAGNESIUM** kan die effek van die medisyne verminder. Om hierdie interaksie te vermy, neem **BONE BUILDER WITH MAGNESIUM** ten minste 2 ure voor of na antibiotika.

#### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: hoë kalsiumvlakke (hiperkalsemie), niersiekte (insluitend nierstene), min of geen maagsuur (achlorhidrie), hartsiekte, siekte van die pankreas, 'n sekere longsiekte (sarkoidose), probleme met die opname van voeding uit voedsel (wanabsorpsiesindroom), diabetes, bloedingversteurings, hartbolk. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: digoksien, sellulose-natriumfosfaat, sekere fosfaatbinders (soos kalsiumasetaat), antikoagulante (Warfarin), diabetiese medikasie, bloeddrukmedikasie. As enige van die volgende gebeur, hou op om **BONE BUILDER WITH MAGNESIUM** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies-uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;
- Naarheid / braking, verlies aan eetlus, ongewone gewigsverlies, geestelike / gemoedsveranderinge, been- / spierpyn, hoofpyn, verhoogde dors / urinering, swakheid, ongewone moegheid.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **BONE BUILDER WITH MAGNESIUM** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nowe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Gastro-intestinale ongemak: Opgeblasenheid, gas of hardwygheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **BONE BUILDER WITH MAGNESIUM** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

#### INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmatreëls**)

#### DOSIS EN AANWYSINGS VIR GEBRUIK

**Volwasse:** Neem een (1) tablet daagliks met etes, of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

#### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie aanvulling, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

#### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

#### Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

#### BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **BONE BUILDER WITH MAGNESIUM** gebruik as u sigbare tekens van agteruitgang opmerk nie.

#### IDENTIFIKASIE

Wit, langwerpige bedekte tablet.

#### AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêl, peuterkrimpsêl, spons en silikagelsakkie.

#### REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

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

#### NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146,

Tel: 011- 802-8101

#### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.