

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

BONE BUILDER® FORTE,

90 Capsules

COMPOSITION

Each one (1) capsule of BONE BUILDER® FORTE contain the following actives:

Microcrystalline Hydroxyapatite Concentrate	950 mg
(Providing elemental calcium 210 mg and elemental phosphorus 80 mg)	
Vitamin D (as Cholecalciferol)	25 µg (1 000 I.U.)

Inactive Ingredients : Capsule (hydroxypropylmethylcellulose), magnesium stearate (vegetable), microcrystalline cellulose and stearic acid (vegetable). **This product is non-GMO (Sugar Free)**

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

BONE BUILDER® FORTE provides bone health support with microcrystalline hydroxyapatite concentrate (MCHC), a highly absorbable crystalline compound that provides everything found in healthy bones and is backed by more than 30 years of research. MCHC contains naturally occurring calcium, phosphorus, and trace amounts of other minerals, bone growth factors, collagen and other vital bone proteins. This formula is designed to support bone mineral density and also features vitamin D for enhanced bone health support.

Ingredients	Uses for ingredient
Microcrystalline Hydroxyapatite Concentrate	MCHC can increase bone mineral density by reducing bone resorption, which is the process of breaking down bones to release calcium into the blood.
Vitamin D (as Cholecalciferol)	Cholecalciferol (vitamin D3) is also used along with calcium to prevent and treat bone diseases.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **BONE BUILDER® FORTE** 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.

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® FORTE** 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;



These are all very serious effects. If you have them, you may have had a serious reaction to **BONE BUILDER® FORTE**. 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® FORTE**. 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**)

DOSE AND DIRECTIONS FOR USE

Adults: Take one (1) capsule daily 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® FORTE** if you notice visible signs of deterioration.

IDENTIFICATION

Clear vegetable capsule with white powder.

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® FORTE,

90 Kapsule

SAMESTELING

Elke (1) kapsule BONE BUILDER® FORTE bevat die volgende aktiewe stowwe:

Mikrokristallyne hidroksiapatiet konsentraat 950 mg

(Die verskaffing van elementêre kalsium 210 mg en

elementêre fosfor 80 mg)

Vitamiën D (as Cholecalciferol) 25 µg (1 000 IE)

Onaktiewe bestanddele: Kapsule (hydroxypropylmethylcellulose), magnesium stearaat (groente), mikrokristallyne sellulose en steariensuur (groente). **Hierdie produk is nie-GGO (suikervry)**

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

BONE BUILDER® FORTE bied ondersteuning vir beengesondheid met mikrokristallyne hidroksiapatietkonsentraat (MCHC), 'n hoogs absorbeerbare kristallyne verbinding wat alles verskaf wat gevind word in gesonde bene en word gerugsteun deur meer as 30 jaar se navorsing. MCHC bevat natuurlik voorkomende kalsium, fosfor en spoorhoeveelheid van ander minerale, beengroefaktore, kollageen en ander belangrike beenproteïene. Hierdie formule is ontwerp om te ondersteun beenmineraaldigtheid en bevat ook vitamien D vir verbeterde ondersteuning vir beengesondheid.

Bestanddele	Gebruike vir bestanddeel
Mikrokristallyne hidroksiapatiet konsentraat	MCHC kan beenmineraaldigtheid verhoog deur beensorsorpsie te verminder, wat die proses is om bene af te breek om kalsium in die bloed vry te stel.
Vitamiën D (as Cholecalciferol)	Cholecalciferol (vitamiën D3) word ook saam met kalsium gebruik om beensiektes te voorkom en te behandel.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **BONE BUILDER® FORTE** 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.

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), hartsiektes, siekte van die pankreas, 'n sekere longsiekte (sarkoidose), probleme met die opname van voeding uit voedsel (wanabsorpsiesindroom), diabetiese, bloedingsversteurings, hartblok. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: digoksien, sellulose-natriumfosfaat, sekere fosfaatbinders (soos kalsiumasetaat), antikoagulant (Warfarin), diabetiese medikasie, bloeddrukmedikasie. As enige van die volgende gebeur, hou op om **BONE BUILDER® FORTE** 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;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **BONE BUILDER® FORTE** gehad. Vir 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® FORTE** 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 voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem een (1) kapsule daaglik 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® FORTE** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Duidelik groentekapsule met wit poeier.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêël, peuterkrimpsêël, 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.