

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

BONE BUILDER® CHEWABLE,

90 Chewable Tablets

COMPOSITION

Each one (1) tablet of BONE BUILDER® CHEWABLE contain the following actives:

Microcrystalline Hydroxyapatite Concentrate (providing elemental calcium 57 mg and elemental phosphorus 22,5 mg)	250 mg
Dicalcium phosphate (providing elemental calcium 46,33 mg and elemental phosphorus 34,5 mg)	189,5 mg
Magnesium (as magnesium glycinate)	25 mg
Zinc (as zinc citrate)	2 mg
Copper (as copper lysinate HCl)	0,25 mg
Manganese (as manganese citrate)	0,25 mg
Vitamin D (as cholecalciferol)	0,6 µg (25 I.U.)

Inactive Ingredients: Guar gum, natural flavours, organic cocoa powder, silica and stearic acid (vegetable).

Contains Sugar: Fructose (441,5 mg), Sorbitol (1000,6 mg)

This product is non-GMO (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION - Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

BONE BUILDER® CHEWABLE provides bone health support with microcrystalline hydroxyapatite concentrate (MCHC), a highly absorbable crystalline compound that provides naturally occurring components of bone 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 well-rounded formula is designed to support bone mineral density and also features vitamin D and magnesium for enhanced bone health support.

Ingredients	Uses for ingredient
Microcrystalline Hydroxyapatite Concentrate	MCHC is a matrix of calcium, other minerals, and organic compounds like collagen and bone-growth peptides. It's chemically similar to human bone and is bioactive and living
Dicalcium phosphate	Dicalcium phosphate operates primarily by contributing essential calcium and phosphorus to the body.
Magnesium (as magnesium glycinate)	Magnesium glycinate is a supplement that combines magnesium with the amino acid glycine. It is highly bioavailable.
Zinc (as zinc citrate)	Zinc is a component of bone tissue and plays a role in bone mineralization and
Copper (as copper lysinate HCl)	It helps maintain healthy bones, blood vessels, nerves, and immune function, and it contributes to iron absorption.
Manganese (as	Manganese may help support bone
Vitamin D (as cholecalciferol)	Vitamin D is important for bone health because it helps the body absorb calcium and supports muscles

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **BONE BUILDER® CHEWABLE** 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. **Antibiotics:** Should you be taking any antibiotics, please ensure that you take **BONE BUILDER® CHEWABLE** at least two (2) hours before or after your prescribed medication.

WARNING AND SPECIAL PRECAUTIONS

Contains fructose which may have an effect on the glycaemic control of patients with diabetes mellitus. Contains sorbitol and may have a laxative effect.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Hypercalcemia, 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), caution is advised if you have diabetes, liver disease, phenylketonuria (PKU), Alcohol use disorder, Surgery for weight-loss (bariatric surgery), Copper deficiency, Wilson disease, Iron-deficiency anaemia, Hardening of the arteries (atherosclerosis), A type of fungal infection called histoplasmosis, High levels of calcium in the blood, Over-active parathyroid gland (hyperparathyroidism), Lymphoma, A disease that causes swelling (inflammation) in body organs, usually the lungs or lymph nodes (sarcoidosis), Tuberculosis. If you are taking the following medication, please consult with your healthcare professional before taking: Blood pressure medications, Calcium-channel blockers, Antacids that contain aluminum, tetracycline antibiotics (such as doxycycline, minocycline), estramustine, levothyroxine, and quinolone antibiotics (such as ciprofloxacin, levofloxacin), bisphosphonate (for example, alendronate), a thyroid medication (for example, levothyroxine), Penicillamine (Cuprimine, Depen), medications for HIV/AIDS (Integrase inhibitors), Birth control pills (Contraceptive drugs), medications for mental conditions (Antipsychotic drugs), Digoxin (Lanoxin), Water pills (Thiazide diuretics), Atorvastatin (Lipitor). If any of the following happens, stop using **BONE BUILDER® CHEWABLE** 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® CHEWABLE**. 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® CHEWABLE**. 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: Chew one (1) to three (3) tablets once daily or as directed by your healthcare practitioner. Chew or crush tablets completely before swallowing. Do not swallow tablets whole.

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® CHEWABLE** if you notice visible signs of deterioration.

IDENTIFICATION

Light brown, speckled, uncoated round 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® CHEWABLE,

90 koubare tablette

SAMESTELING

Elke (1) tablet BONE BUILDER® CHEWABLE bevat die volgende aktiewe stowwe:

Mikrokristallyne hidroksiapatietkonsentraat (verskaf elementêre kalsium 57 mg en elementêre fosfor 22,5 mg)	250 mg
Dikalsiumfosfaat (verskaf elementêre kalsium 46,33 mg en elementêre fosfor 34,5 mg)	189,5 mg
Magnesium (as magnesiumglisinaat)	25 mg
Sink (as sinkisitraat)	2 mg
Koper (as koperlysiinaat HCl)	0,25 mg
Mangaan (as mangaansitraat)	0,25 mg
Vitamiën D (as cholecalciferol)	0,6 µg (25 IE)

Onaktiewe bestanddele: Gurgom, natuurlike geure, organiese kakaopoeier, silika en steariensuur (groente).

Bevat suiker: Fruktose (441,5 mg), Sorbitol (1000,6 mg)

Hierdie produk is nie-GGO.

FARMAKOLOGIESE KLASIFIKASIE - Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

BONE BUILDER® CHEWABLE bied ondersteuning vir beengesondheid met mikrokristallyne hidroksiapatietkonsentraat (MCHC), 'n hoogs absorbeerbare kristallyne verbinding wat natuurlike komponente van been verskaf en gerugsteun word deur meer as 30 jaar se navorsing. MCHC bevat natuurlike kalsium, fosfor en spoorhoeveelheid van ander minerale, beengroefaktore, kollageen en ander belangrike beeenproteïene. Hierdie afgeonde formule is ontwerp om beenmineraaldigtheid te ondersteun en bevat ook vitamien D en magnesium vir verbeterde beengesondheid ondersteuning.

Bestanddele	Gebruik vir bestanddeel
Mikrokristallyne hidroksiapatiet konsentraat	MCHC is 'n matrys van kalsium, ander minerale en organiese bindingssoos kollageen en beengroei-peptiede. Dit is chemies soortgelyk aan menslike been en is bioaktief en lewend
Dikalsiumfosfaat	Dikalsiumfosfaat werk hoofsaaklik deur noodsaaklike kalsium en fosfor tot die liggaam by te dra.
Magnesium (as magnesiumglisinaat)	Magnesiumglysinaat is 'n aanvulling wat magnesium kombineer met die aminosuur glisien. Dit is hoogs bio-essensieel, wat beteken dat dit maklik deur die dunderm geabsorbeer word.
Sink (as sinkisitraat)	Sink is 'n komponent van beenweefsel en speel 'n rol in beenmineralisasie en metabolisme.
Koper (as koperlysiinaat HCl)	Dit help om gesonde bene, bloedvate, senuwees en immuunfunksie te handhaaf, en dit dra by tot ysterabsorpsie.
Mangaan (as mangaansitraat)	Mangaan kan help om beenmineraaldigtheid te ondersteun wanneer dit met kalsium, sink en koper gekombineer word.
Vitamiën D (as cholecalciferol)	Vitamiën D is belangrik vir beengesondheid omdat dit die liggaam help om kalsium op te neem en spiere ondersteun

KONTRA-INDIKASIES:

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

Antibiotika: As jy enige antibiotika neem, maak asseblief seker dat jy **BONE BUILDER® CHEWABLE** ten minste twee (2) ure voor of na jou voorgeskrewe medisyne neem.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Bevat fruktose wat 'n effek kan hê op die glukemiese beheer van pasiënte met diabetes mellitus. Bevat sorbitol en 'n lakseermiddel hê. Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hiperkalsemie, 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), versigtigheid word aangeraai as jy diabetes het, lewiersiekte, fenielketonurie (PKU), Alkoholgebruiksversteuring, Chirurgie vir gewigverlies (bariatrisie chirurgie), Kopertekort, Wilson-siekte, Ystertekortanemie, Verharding van die are (aterosklerose), 'n Tipe swaminfeksie genaamd histoplasma. Hoë vlakke van kalsium in die bloed, Ooraktiewe paratiroïedklier (hiperparatiroïedisme), Limfoom, 'n Siekte wat swelling (inflammasie) in liggaamsorgane veroorsaak, gewoonlik die longe of limfknope (sarkoidose), Tuberkulose. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Bloeddruk medisyne, kalsiumkanaalblokkers, teenuurmiddels wat aluminium bevat, tetrasikline antibiotika (soos doksisiklien, minosiklien), estramustien, levotiroksien en kinolon antibiotika (soos ciprofloksien, levofloksien), bisfosfonaat (byvoorbeeld alendronaat), 'n skildklier medisyne (byvoorbeeld levotiroksien), Penisilamine (Cuprimine, Depen), medisyne vir MIV / vigs (integrase-remmers), geboortebeperkingspille (voorbehoedmiddels), medisyne vir geestesstoestand (antipsigotiese middels), digoksien (lanoksien), waterpille (tiazieddiuretika), atorvastatin (lipitor). As enige van die volgende gebeur, hou op om **BONE BUILDER® CHEWABLE** 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® CHEWABLE** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):
- Gastro-intestinale ongemak: Opgeblasenheid, gas of hardwigheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **BONE BUILDER® CHEWABLE** 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 gelyk 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: Kou een (1) tot drie (3) tablette een keer per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn. Kou of verpletter tablette heeltemal voordat jy sluk. Moenie tablette heel sluk nie. **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.

Beskermer teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

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

Moenie **BONE BUILDER® CHEWABLE** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Ligbruin, gespikkelde, onbedekte ronde tablet.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, indusiesel, peuterkrimpseël, spons en silikagelsakke.

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 BESIGHEIDSAADRES VAN APPLIKANT

Versprei deur:

Ampiro 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.

