

PATIENT INFORMATION LEAFLET

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

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **BONE BUILDER® FORTE** is available without a doctor's prescription.
- Nevertheless, you still need to use **BONE BUILDER® FORTE** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **BONE BUILDER® FORTE** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **BONE BUILDER® FORTE** is and what it is used for.
- What you need to know before you take **BONE BUILDER® FORTE**.
- How to take **BONE BUILDER® FORTE**.
- Possible side effects.
- How to store **BONE BUILDER® FORTE**.
- Contents of the pack and other information.

WHAT BONE BUILDER® FORTE CONTAINS

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

Microcrystalline Hydroxyapatite Concentrate (Providing elemental calcium 210 mg and elemental phosphorus 80 mg)	950 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)**

WHAT BONE BUILDER® FORTE IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE BONE BUILDER® FORTE

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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.

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

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, do not take if you are pregnant or breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **BONE BUILDER® FORTE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **BONE BUILDER® FORTE** may affect you.

TAKING OTHER MEDICINES WITH BONE BUILDER® FORTE

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner.

HOW TO TAKE BONE BUILDER® FORTE

Do not share medicines prescribed for you with any other person. Always take **BONE BUILDER® FORTE** exactly as described in this leaflet, or as your doctor, healthcare practitioner has instructed you. You should check with your doctor, pharmacist or healthcare practitioner if you are unsure.

Directions for use:

Adults: Take one (1) capsule daily or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

IF YOU TAKE MORE BONE BUILDER® FORTE THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.



IF YOU FORGET TO TAKE BONE BUILDER® FORTE

Do not take a double dose to make up for a missed dose.

POSSIBLE SIDE EFFECTS

BONE BUILDER® FORTE may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **BONE BUILDER® FORTE** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **BONE BUILDER® FORTE**.

STORAGE AND DISPOSING OF BONE BUILDER® FORTE

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **BONE BUILDER® FORTE** if you notice visible signs of deterioration.

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

PRESENTATION OF BONE BUILDER® FORTE

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

IDENTIFICATION OF BONE BUILDER® FORTE

Clear vegetable capsule with white powder.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

19 November 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
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Sandton, 2146
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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.
Dissipline: Gesondheidsaanvulling
34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

BONE BUILDER® FORTE,

90 Kapsule

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **BONE BUILDER® FORTE** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **BONE BUILDER® FORTE** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **BONE BUILDER® FORTE** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **BONE BUILDER® FORTE** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **BONE BUILDER® FORTE** neem.
- Hoe om **BONE BUILDER® FORTE** te neem.
- Moontlike newe-effekte.
- Hoe om **BONE BUILDER® FORTE** te bêre.
- Inhoud van die pak en ander inligting

WATTER BONE BUILDER® FORTE BEVAT

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

Mikrokristallyne hidroksiapatietkonsentraat	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)

WAT IS BONE BUILDER® FORTE KAPSULE EN WAARVOOR WORD DIT GEBRUIK

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 spoorhoeveelthede van ander minerale, beengroeffaktore, kollageen en ander belangrike beengrepeente. Hierdie formule is ontwerp om te ondersteun beeminaeraligheid en bevat ook vitamien D vir verbeterde ondersteuning vir beengesondheid.

VOORDAT JY BONE BUILDER® FORTE NEEM

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 voordat jy hierdie aanvulling neem. Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, moenie neem as jy swanger is of borsvoed nie. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

BESTUUR EN GEBRUIK VAN MASIENE

Dit is nie altyd moontlik om te voorspel in watter mate **BONE BUILDER® FORTE** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **BONE BUILDER® FORTE** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET BONE BUILDER® FORTE

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

HOE OM BONE BUILDER® FORTE TE NEEM

Moenie medisyne wat vir u voorskryf is, met enige ander persoon deel nie. Neem altyd **BONE BUILDER® FORTE** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:

Volwasse: Neem een (1) kapsule daaglik of soos voorskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER BONE BUILDER® FORTE NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGEET OM BONE BUILDER® FORTE TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

MOONTLIKE NEWE-EFFEKTE

BONE BUILDER® FORTE kan newe-effekte hê.

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, bloedingsversteurings, hartblik. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: digikose, sellulose-natriumfosfaat, sekere fosfaatbinders (soos kalsiumasetaat), antikoagulanse (Warfarin), diabetes medikasie, bloeddrukmedikasie. As enige van die volgende gebeur, hou op om **BONE BUILDER® FORTE** te gebruik en vertel jou dokter of gaan na die ongevalde-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. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

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

Nie alle newe-effekte en interaksies wat vir **BONE BUILDER® FORTE** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **BONE BUILDER® FORTE**.

HOE OM BONE BUILDER® FORTE TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking. 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. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN BONE BUILDER® FORTE

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

IDENTIFIKASIE VAN BONE BUILDER® FORTE

Duidelik groentekapsule met wit poeier.

REGISTRASIE NOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERËEN OP

19 November 2024

NAAM EN ADRES VAN REGISTRASIEHOUEUR

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