

## 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® CHEWABLE,

#### 90 Chewable Tablets

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS

IMPORTANT INFORMATION FOR YOU

- **BONE BUILDER® CHEWABLE** is available without a doctor's prescription.
- Nevertheless, you still need to use **BONE BUILDER® CHEWABLE** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **BONE BUILDER® CHEWABLE** 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® CHEWABLE** is and what it is used for.
- What you need to know before you take **BONE BUILDER® CHEWABLE**.
- How to take **BONE BUILDER® CHEWABLE**.
- Possible side effects.
- How to store **BONE BUILDER® CHEWABLE**.
- Contents of the pack and other information.

#### WHAT BONE BUILDER® CHEWABLE CONTAINS

Each one (1) tablet of **BONE BUILDER® CHEWABLE** contains 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.**

#### WHAT BONE BUILDER® CHEWABLE IS AND WHAT IT IS USED FOR

**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.

#### BEFORE YOU TAKE BONE BUILDER® CHEWABLE

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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. 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® CHEWABLE** 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® CHEWABLE** may affect you.

#### TAKING OTHER MEDICINES WITH BONE BUILDER® CHEWABLE

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® CHEWABLE

Do not share medicines prescribed for you with any other person. Always take **BONE BUILDER® CHEWABLE** 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.

#### IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF BONE BUILDER® CHEWABLE:

**BONE BUILDER® CHEWABLE** contains fructose which may have an effect on the control of your blood sugar if you have diabetes mellitus. **BONE BUILDER® CHEWABLE** contains sorbitol and may have a laxative effect.



#### 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.**

#### IF YOU TAKE MORE BONE BUILDER® CHEWABLE THAN YOU SHOULD

In the event of overdosage, 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® CHEWABLE

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

#### POSSIBLE SIDE EFFECTS

**BONE BUILDER® CHEWABLE** may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Hypercalcaemia, high calcium levels (hypercalcaemia), 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, Overactive 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 practitioner 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.

Not all side effects and interactions reported for **BONE BUILDER® CHEWABLE** 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® CHEWABLE**.

#### STORAGE AND DISPOSING OF BONE BUILDER® CHEWABLE

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® CHEWABLE** 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® CHEWABLE

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

#### IDENTIFICATION OF BONE BUILDER® CHEWABLE

Light brown, speckled, uncoated round tablet.

**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 December 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

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