

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

**S0**

### Bioplus Booster Mocha Syrup

Caffeine (anhydrous).....	90 mg/10 ml
Calcium gluconate.....	300 mg/10 ml
providing Calcium (elemental).....	27,9 mg/10 ml
Calcium citrate.....	60 mg/10 ml
providing Calcium (elemental).....	12,6 mg/10 ml
Nicotinamide (Vitamin B <sub>3</sub> ).....	8 mg/ 10 ml
Thiamine hydrochloride (Vitamin B <sub>1</sub> ).....	5,33 mg/10 ml
Riboflavin sodium phosphate (Vitamin B <sub>2</sub> ).....	3,67 mg/10 ml
d-Pantothenol (Vitamin B <sub>5</sub> ).....	3,66 mg/10 ml
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> ).....	3 mg/10 ml
Cyanocobalamin (Vitamin B <sub>12</sub> ) 0,1 % in mannitol...	4 µg/10 ml

Contains sugars: Sucrose 2,40 g/10 ml, Liquid glucose 2,90 g/10 ml, Mannitol 8 mg/10 ml

Contains artificial sweeteners: Saccharin sodium 500 1,33 mg/10 ml, Sodium cyclamate 13,30 mg/10 ml, Dolsweet 16 Dolcre [ADI 450 Sweetener Blend] 11,00 mg/10 ml

### Category D: Complementary Medicine

#### Health Supplements: D34.12 Multiple Substance Formulation

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

### Read all of this leaflet carefully because it contains important information for you.

Bioplus Booster Mocha Syrup is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take Bioplus Booster Mocha Syrup carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Bioplus Booster Mocha Syrup with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

### What is in this leaflet

1. What Bioplus Booster Mocha Syrup is and what it is used for
2. What you need to know before you take Bioplus Booster Mocha Syrup
3. How to take Bioplus Booster Mocha Syrup

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4. Possible side effects
5. How to store Bioplus Booster Mocha Syrup
6. Contents of the pack and other information

### **1. What Bioplus Booster Mocha Syrup is and what it is used for**

Bioplus Booster Mocha Syrup is a tonic containing caffeine, the B- vitamins and calcium. Caffeine has been known to increase mental alertness resulting in a rapid and clearer flow of thought. It further reduces the feelings of fatigue and drowsiness resulting in an enhanced state of mind.

The B group vitamins assist in the metabolism of fatty acids, carbohydrates and protein for energy release and production. They are also involved in the maintenance of a healthy nervous system. Calcium assists in muscle contractility as well as myocardial conduction. It also maintains and promotes the growth of strong bones and teeth.

### **2. What you need to know before you take Bioplus Booster Mocha Syrup**

#### **Do not take Bioplus Booster Mocha Syrup:**

- If you are hypersensitive (allergic) to the active ingredients or any of the other ingredients (listed in section 6).
- If you have liver failure, and other disorders with the bile duct.
- If you have genetic eye disease.
- If you have calcium kidney stones, or a history of kidney stones.
- If you have kidney failure and are taking aluminium compounds.

#### **Warnings and precautions**

Take special care with Bioplus Booster Mocha Syrup:

- If you have an active stomach ulcer or reduced blood flow to the heart, with or prone to gout, or in those who consume large amounts of alcohol.
- If you have diabetes mellitus.
- Contains sucrose and glucose: patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take Bioplus Booster Mocha Syrup.
- If you have kidney disease, or diseases associated with increased calcium levels.
- If you are taking caffeine and / or theophylline.
- Caffeine tolerance occurs rapidly to the stimulating effects of caffeine, physical signs of withdrawal including irritability, restlessness, lethargy, and headache may occur if intake is stopped abruptly.
- Use of caffeine with medicines that increase blood pressure (e.g., bitter orange extract, synephrine, octopamine, ephedra, ephedrine) is not recommended. If you are taking

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beta blockers.

- Consult a registered health care professional if you are taking any other medicine (such as lithium) including chronic, complementary or traditional medicines; or have high blood pressure, glaucoma, and/or overactive bladder syndrome.
- Consumption with other caffeine-containing products or foods (e.g., medications, coffee, tea, colas, cocoa, guarana maté) is not recommended.
- Discontinue use two weeks prior to surgery.
- Total caffeine intake more than 200 mg per day is not recommended during pregnancy and breastfeeding.
- 90 mg of caffeine in each dosage unit (10 ml). A cup of instant coffee contains approximately 80 mg of caffeine.
- Use of caffeine may result in sleep deprivation.
- Cyanocobalamin should not be given before a diagnosis of subacute degeneration of the spinal cord, or if pernicious anaemia has been fully established, as these symptoms may be masked.
- Large doses of Riboflavin sodium phosphate (Vitamin B<sub>2</sub>) may result in a change in the colour of urine, which may interfere with certain laboratory results.
- long-term use of large doses of Pyridoxine hydrochloride (Vitamin B<sub>6</sub>) is linked with the development of pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.

### Children and adolescents

Do not use Bioplus Booster Mocha Syrup in children and adolescents under the age of 18 years.

### Other medicines and Bioplus Booster Mocha Syrup

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- **Aspirin** may prolong the effect of Nicotinamide.
- **Albuterol, metaproterenol, terbutaline, isoproterenol** may cause low potassium levels.
- **Calcium** salts reduce the absorption of bisphosphonate (alendronate, ibandronate, risedronate)
- IV **chloramphenicol** may weaken the effect of vitamin B<sub>12</sub> in anaemia.
- Use of caffeine with **corticosteroids and/or diuretics** can cause low potassium levels.
- Use of caffeine with medicines that increase blood pressure (e.g., **bitter orange**

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**extract, synephrine, octopamine, ephedra, ephedrine**) is not recommended.

- Calcium salts will weaken the effects of some **fluorides, fluoroquinolones (ciprofloxacin, gemifloxacin, levofloxacin, moxifloxacin), tetracyclines (doxycycline, minocycline)**.
- Nicotinamide decreases the effects of **insulin or oral hypoglycaemics**.
- Pyridoxine reduces the effects of **levodopa**, but this does not occur if a dopa decarboxylase inhibitor is also given.
- **Oral Contraceptives** may weaken the effects of cyanocobalamin.
- Pyridoxine reduces the effects of **Phenytoin & Phenobarbital**.
- **Statins** taken with nicotinamide may increase the risk of muscle disease.
- Calcium enhances the effects of digitalis on the heart and may precipitate digitalis intoxication.

### Medicines that may decrease vitamin levels in the body:

<b>Pyridoxine</b>	Hydralazine, Isoniazid, Penicillamine, Oral contraceptives.
<b>Cyanocobalamin</b>	Neomycin, Aminosalicilic acid, Histamine H2-antagonists, Omeprazole, Colchicine, Oral contraceptives
<b>Calcium</b>	Corticosteroids
<b>Caffeine</b>	Phenytoin, Phenobarbital, Felbamate, Ethosuximide, Carbamazepine, Valproate, Ritonavir, Rifampicin, and sulfinpyrazone.

### Medicines that may increase vitamin levels in the body:

<b>Calcium</b>	Thiazide diuretics, Vitamin D
<b>Caffeine</b>	Allopurinol, some antiarrhythmics, Cimetidine, Disulfiram, Fluvoxamine, Interferon alfa, Macrolide antibacterials, Quinolones, Oral contraceptives, Tiabendazole, Viloxazine.

### Bioplus Booster Mocha Syrup with food

- **Bran** weakens the effects of calcium.

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### **Pregnancy and breastfeeding**

Mothers should closely monitor their intake of caffeine. Caffeine crosses the human placenta but is not a factor which can cause the malformation of an embryo. Caffeine peaks in breast milk approximately 1-2 hours after consumption by the mother.

Total caffeine intake of more than 200 mg per day is not recommended during pregnancy or breastfeeding.

If you are of childbearing age, pregnant or breastfeeding and have concerns that your daily intake of caffeine from all sources may exceed 200 mg per day, please consult a relevant health care provider prior to use.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this health supplement.

### **Driving and using machines**

The influence of Bioplus Booster Mocha Syrup on the ability to drive and use machines is not known. It is not always possible to predict to what extent Bioplus Booster Mocha Syrup may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Bioplus Booster Mocha Syrup affects them.

### **Bioplus Booster Mocha Syrup contains:**

- Riboflavin sodium phosphate (Vitamin B<sub>2</sub>), which in large doses results in a change in the colour of urine, which may interfere with certain laboratory results.
- Pyridoxine hydrochloride (Vitamin B<sub>6</sub>) whose long-term use in large doses is linked with the development of pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.
- 

### **Bioplus Booster Mocha Syrup contains sugars and sweeteners:**

- Sucrose and glucose which may have an effect on the control of your blood sugar if you have diabetes mellitus.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Bioplus Booster Mocha Syrup.
- Contains artificial sweeteners: Saccharin sodium 500 1,33 mg/10 ml, Sodium cyclamate 13,30 mg/10 ml, Dolsweet 16 Dolcre [ADI 450 Sweetener Blend] 11,00 mg/10 ml.
- Contains glucose which may be harmful to the teeth.

### **Bioplus Booster Mocha Syrup contains alcohol:**

- 843 mg of alcohol (ethanol) in each dosage unit (10 ml). The amount in 10 ml of Bioplus Booster Mocha Syrup is equivalent to 2 ml of beer or 0.8 ml of wine.

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- The amount of alcohol is not likely to have an effect in adults.
- The alcohol in this health supplement may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.
- If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

### **Bioplus Syrup Mocha contains preservatives:**

- Methyl parahydroxybenzoate (E218) and Propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

### **Bioplus Booster Mocha Syrup contains sodium:**

- Bioplus Booster Original contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

### **3. How to take Bioplus Booster Mocha Syrup**

Always use Bioplus Booster Mocha Syrup exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The usual dose is:

Adults over 18 years of age: 10 ml or 2 medicine measures three times a day, after meals.

- **For occasional use only. Do not exceed the recommended dosage.**
- For oral use, take undiluted.
- Shake well before use.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

### **If you take more Bioplus Booster Mocha Syrup than you should**

- Excessive amounts of calcium may lead to hypercalcaemia. Symptoms of hypercalcaemia include anorexia, nausea, vomiting, constipation, abdominal pain, muscle weakness, mental disturbances, increased thirst, excessive urination, increased calcium in the kidneys, kidney stones, and, in severe cases, irregular heartbeats and coma.
- At doses of more than 600 mg per day, caffeine may cause anxiety, rapid heart rate, palpitations, insomnia, restlessness, nervousness, tremor and headache.
- Treatment is symptomatic and supportive.
- Caffeine overdose may lead to maniacal behaviour, diuresis and repeated vomiting with extreme thirst, tremor, delirium, hyperthermia, tachycardia, tachypnoea, electrolyte disturbances, convulsions and death.

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- In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to take Bioplus Booster Mocha Syrup**

Do not take a double dose to make up for forgotten individual doses.

### **If you stop taking Bioplus Booster Mocha Syrup**

You can stop taking Bioplus Booster Mocha Syrup at any time.

If you have any further questions on the use of Bioplus Booster Mocha Syrup, ask your doctor or pharmacist.

### **4. Possible side effects**

Bioplus Booster Mocha Syrup can have side effects.

Side effects reported include gastrointestinal disturbances (constipation, bloating and gas), fever, chills, hot flushing, dizziness, malaise, acneform and bullous eruptions, and tremor.

Not all side effects reported for Bioplus Booster Mocha Syrup are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Bioplus Booster Mocha Syrup, please consult your health care provider for advice.

If any of the following happens, stop taking Bioplus Booster Mocha Syrup and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- severe rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to Bioplus Booster Mocha Syrup. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following:

*Side effects with unknown frequency:*

- gastrointestinal disturbances
- fever, chills, hot flushing, dizziness, general discomfort
- skin disorders
- tremor

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects directly to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side affects you can help provide more information on the safety of Bioplus Booster Mocha Syrup.

### 5. How to store Bioplus Booster Mocha Syrup

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in a cool, dry place at or below 25 °C. Protect from light.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist for proper disposal.

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

### 6. Contents of the pack and other information

#### What Bioplus Booster Mocha Syrup contains

The active ingredients are:

<b>Each 10 ml contains:</b>	
Caffeine (anhydrous)	90 mg
Calcium gluconate	300 mg
providing Calcium (elemental)	27,9 mg
Calcium citrate	60 mg
providing Calcium (elemental)	12,6 mg
Nicotinamide (Vitamin B <sub>3</sub> )	8 mg
Thiamine hydrochloride (Vitamin B <sub>1</sub> )	5,33 mg
Riboflavin sodium phosphate (Vitamin B <sub>2</sub> )	3,67 mg
d-Pantothenol (Vitamin B <sub>5</sub> )	3,66 mg
Pyridoxine hydrochloride (Vitamin B <sub>6</sub> )	3 mg
Cyanocobalamin (Vitamin B <sub>12</sub> ) 0,1 % in mannitol	4 µg



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The other ingredients are Sucrose, Liquid Glucose (43 Neutral), Sodium Chloride BP, Saccharin Sodium 500, Mannitol (E421) - [Cyanocobalamin (Vitamin B12) 0,1 % in mannitol], Sodium Cyclamate

Citric Acid Monohydrate, Hydrochloric Acid 32 % (pH adjustment) Ethanol 96,5 %, Dolsweet 16 Dolcre - [ADI 450 Sweetener Blend],

Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Flavour Mocha 507282 T, Purified Water

### **What Bioplus Booster Mocha Syrup looks like and contents of the pack**

Bioplus Booster Mocha Syrup is a clear yellow liquid with a mocha odour in 10 ml sachets (laminated plastic/foil) containing 10 ml of syrup and in 30 ml bottles (amber glass) containing 30 ml of syrup.

Pack sizes: 10 ml and 30 ml. Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

Adcock Ingram Limited

1 New Road

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Midrand 1965

Customer Care: 0860 ADCOCK/232625

### **This leaflet was last revised in**

15 August 2023

### **Registration number**

To be allocated.

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adcock ingram 

Date of Approval: 15 August 2023

## PASIËNT INLIGTING VOUBILJET

### SKEDULERINGSSTATUS:

**S0**

### Bioplus Booster Mokka Stroop

Kafeïen (watervry).....	90 mg/10 ml
Kalsium glukonaat.....	300 mg/10 ml
voorsien Kalsium (elementeel).....	27,9 mg/10 ml
Kalsium sitraat.....	60 mg/10 ml
voorsien Kalsium (elementeel).....	12,6 mg/10 ml
Nikotinamied (Vitamien B3).....	8 mg/ 10 ml
Tiamien hidrochloried (Vitamien B1).....	5,33 mg/10 ml
Riboflaviën natrium fosfaat (Vitamien B2).....	3,67 mg/10 ml
d-Pantotenol (Vitamien B5).....	3,66 mg/10 ml
Piridoksien hidrochloried (Vitamien B6).....	3 mg/10 ml
Sianokobalamien (Vitamien B12) 0.1% mannitol.....	4 µg/10 ml

Bevat suiker: Sukrose 2,40 g/10 ml, Vloeibare glukose 2,90 g/10 ml

Bevat kunsmatige versoeters: Sakkarien natrium 500 1,33 mg/10 ml, Natriumsiklamaat 13,30 mg/10 ml, Dolsweet 16 Dolcre [ADI 450 Versoeter Mengsel] 11,00 mg/10 ml

### Kategorie D: Aanvullende Medisyne

#### Gesondheid Aanvullings: D34.12 Meervoudige Stof Formulering

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

**Lees hierdie voubiljet noukeurig, want dit bevat belangrike inligting. Bioplus Booster Mokka Stroop is beskikbaar sonder 'n dokter se voorskrif vir u om u gesondheid in stand te hou. Nietemin, u moet nogsteeds Bioplus Booster Mokka Stroop versigtig gebruik om die beste resultate daarvan te kry.**

- Hou hierdie voubiljet. U mag dalk weer deur dit wil lees.
- Moenie Bioplus Booster Mokka Stroop met enige ander persoon deel nie.
- Vra u gesondheidsdiensverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter raadpleeg as u simptome vererger of nie verbeter na 7 dae nie.

### Die inhoud van hierdie voubiljet

1. Wat Bioplus Booster Mokka Stroop is en waarvoor dit gebruik word
2. Wat u moet weet voordat u Bioplus Booster Mokka Stroop gebruik
3. Hoe om Bioplus Booster Mokka Stroop te gebruik

## PASIËNT INLIGTING VOUBILJET

4. Moontlike newe-effekte
5. Hoe om Bioplus Booster Mokka Stroop te bêre
6. Inhoud van die pak en ander inligting

### **1. Wat Bioplus Booster Mokka Stroop is en waarvoor dit gebruik word**

Bioplus Booster Mokka Stroop is 'n tonikum wat kafeïen, die B-vitamiene en kalsium bevat. Dit is bekend dat kafeïen verstandelike waaksaamheid verhoog, wat lei tot 'n vinnige en duideliker denk vloei. Dit verminder verder die gevoelens van moegheid en lomerigheid wat lei tot 'n verbeterde gemoedstoestand.

Die B-groep vitamiene help met die metabolisme van vetsure, koolhidrate en proteïene vir energie vrystelling en produksie. Hulle is ook betrokke by die instandhouding van 'n gesonde senuweestelsel. Kalsium help met spier kontraktiliteit sowel as miokardiale geleiding. Dit handhaaf en bevorder ook die groei van sterk bene en tande.

### **2. Wat u moet weet voordat u Bioplus Booster Mokka Stroop gebruik**

#### **Moenie Bioplus Booster Mokka Stroop in die volgende gevalle gebruik nie:**

- As u hipersensitief (allergies) is vir die aktiewe bestanddele of enige van die ander bestanddele (gelys in afdeling 6).
- As u lewersaking het, en ander afwykings met die galbuis het.
- As u genetiese oogsiekte het.
- As u kalsium nierstene het, of 'n geskiedenis van nierstene het.
- As u nierversaking het en aluminium verbindings gebruik.

#### **Waarskuwings en voorsorgmaatreëls**

Wees versigtig wanneer u Bioplus Booster Mokka Stroop gebruik:

- As u 'n aktiewe maagseer of verminderde bloedvloei na die hart het, met of geneig is tot jig, of in diegene wat groot hoeveelhede alkohol inneem.
- As u suikersiekte het.
- Bevat sukrose en glukose: pasiënte met seldsame oorerflike probleme van fruktose-intoleransie, glukose-galaktose-wan absorpsie of sukrase-isomaltase-ontoereikendheid moet nie Bioplus Booster Mokka Stroop gebruik nie.
- As u niersiekte het, of siektes wat verband hou met verhoogde kalsium vlakke.
- As u kafeïen en / of teofillien gebruik.
- Kafeïen verdraagsaamheid vind vinnig plaas vir die stimulerende effekte van kafeïen, fisiese tekens van onttrekking insluitend prikkelbaarheid, rusteloosheid, lusteloosheid en hoofpyn kan voorkom as inname skielik gestaak word.
- Gebruik van kafeïen saam met medisyne wat bloeddruk verhoog (bv. bitterlemoenekstrak, sinefrien, oktopamien, efedra, efedrien) word nie aanbeveel nie.

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As u betablokkers gebruik.

- Raadpleeg 'n geregistreerde gesondheidswerker as u enige ander medisyne (soos litium) gebruik, insluitend chroniese, aanvullende of tradisionele medisyne; of hoë bloeddruk, gloukoom en/of ooraktiewe blaas sindroom het.
- Verbruik saam met ander kafeïenbevattende produkte of voedsel (bv. medikasie, koffie, tee, cola, kakao, guarana maté) word nie aanbeveel nie.
- Staak gebruik twee weke voor 'n operasie.
- Totale kafeïen inname van meer as 200 mg per dag word nie aanbeveel tydens swangerskap en borsvoeding nie.
- 90 mg kafeïen in elke dosis eenheid (10 ml). 'n Koppie kitskoffie bevat ongeveer 80 mg kafeïen.
- Gebruik van kafeïen kan lei tot slaap gebrek.
- Sianokobalamien moet nie gegee word voor 'n diagnose van sub akute degenerasie van die rugmurg, of as pernisiëuse anemie ten volle vasgestel is nie, aangesien hierdie simptome gemasker kan word.
- Groot dosisse Riboflavin natrium fosfaat (vitamien B2) kan 'n verandering in die kleur van urine tot gevolg hê, wat met sekere laboratorium resultate kan inmeng.
- langtermyn gebruik van groot dosisse Piridoksien hidrochloried (Vitamien B6) word gekoppel aan die ontwikkeling van pyn, gevoelloosheid, tinteling, swelling of spierswakheid in verskillende dele van die liggaam.

### Kinders en tieners

Moenie Bioplus Booster Mokka Stroop gebruik in kinders en tieners onder die ouderdom van 18 jaar nie.

### Ander medisyne en Bioplus Booster Mokka Stroop

Lig altyd u gesondheidsdiensverskaffer in as u enige ander medisyne gebruik. (Dit sluit in alle aanvullende of tradisionele medisyne.)

- **Aspirien kan die effek van Nikotinamied verleng.**
- **Albuterol, metaproterenol, terbutalïen, isoproterenol kan lae kaliumvlakke veroorsaak.**
- **Kalsiumsoute verminder die absorpsie van bisfosfonaat (alendronaat, ibandronaat, risedronaat)**
- Binne-aarse behandeling chlooramfenikol kan die effek van vitamien B12 in anemie verswak.
- Gebruik van kafeïen met kortikosteroïede en/of diuretika kan lae kaliumvlakke veroorsaak.

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- Gebruik van kafeïen saam met medisyne wat bloeddruk verhoog (bv. bitterlemoenekstrak, sinefrien, oktopamien, efedra, efedrien) word nie aanbeveel nie.
- Kalsiumsoute sal die effekte van sommige fluoriede, fluorkinolone (siprofloksasien, gemifloksasien, levofloksasien, moksifloksasien), tetrasikliene (doksisisiklien, minosiklien) verswak.
- Nikotinamied verminder die effek van insulien of orale hipoglukemie.
- Piridoksien verminder die effekte van levodopa, maar dit gebeur nie as 'n dopa-dekarboksilase-inhibeerder ook gegee word nie.
- **Orale Voorbehoedmiddels kan die effekte van sianokobalamien verswak.**
- Piridoksien verminder die effekte van Fenitoïen en Fenobarbitaal.
- **Statiene wat saam met nikotinamied gebruik word, kan die risiko van spiersiekte verhoog.**
- Kalsium versterk die uitwerking van digitalis op die hart en kan digitalis-dronkenskap presipiteer.
- d-Pantotenol moet nie saam met of onmiddellik na parasimpatomimetiese middels of suksametonium gegee word nie.

### Medisyne wat die vitamien vlakke in die liggaam kan laat afneem:

<b>Piridoksien</b>	Hidralasien, Isoniasied, Penisillamien, Orale voorbehoedmiddels.
<b>Sianokobalamien</b>	Neomisien, Aminosalisielsuur, Histamien H2-antagoniste, Omeprazole, Colchicine, Orale voorbehoedmiddels
<b>Kalsium</b>	Kortikosteroïede
<b>Kafeïen</b>	Fenitoïen, Fenobarbitaal, Felbamaat, Etosuksimied, Karbaamasepien, Valproate, Ritonavir, Rifampisien en sulfinyprazone.

### Medisyne wat die vitamien vlakke in die liggaam kan verhoog:

<b>Kalsium</b>	Tiasied diuretika, Vitamien D
<b>Kafeïen</b>	Allopurinol, sommige anti-aritmica, Simetidien, Disulfiram, Fluvoxamine, Interferon alfa, Makrolide antibakteriese middels, Kinolone, Orale voorbehoedmiddels, Tiabendasool, Viloksasien.

## PASIËNT INLIGTING VOUBILJET

### **Bioplus Booster Mokka Stroop met kos**

- **Semels verswak die uitwerking van kalsium.**

### **Swangerskap en borsvoeding**

Moeders moet hul inname van kafeïen noukeurig monitor. Kafeïen kruis die menslike plasenta, maar is nie 'n faktor wat die misvorming van 'n embrio kan veroorsaak nie. Kafeïen piek in borsmelk ongeveer 1-2 uur na verbruik deur die moeder.

Totale kafeïen inname van meer as 200 mg per dag word nie aanbeveel tydens swangerskap en borsvoeding nie.

Indien u van vrugbare ouderdom is, swanger is of borsvoed en bekommerd is dat u daaglikse inname van kafeïen uit alle bronne 200 mg per dag kan oorskry, raadpleeg asseblief 'n relevante gesondheidsdiensverskaffer voor gebruik.

As u swanger is of borsvoed, vermoed u is swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker, of ander gesondheidsdiensverskaffer vir advies voordat u hierdie gesondheid aanvulling gebruik.

### **Bestuur en gebruik van masjinerie**

Die invloed van Bioplus Booster Mokka Stroop op die vermoë om te bestuur en masjinerie te gebruik is onbekend. Dit is nie altyd moontlik om te voorspel tot watter mate Bioplus Booster Mokka Stroop kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet verseker dat hulle nie deelneem aan die bogenoemde aktiwiteite totdat hulle bewus is tot watter mate Bioplus Booster Mokka Stroop hulle affekteer nie.

### **Bioplus Booster Mokka Stroop bevat:**

- Riboflaviën natrium fosfaat (Vitamiën B2), wat in groot dosisse 'n verandering in die kleur van urine tot gevolg het, wat met sekere laboratorium resultate kan inmeng.
- Piridoksien hidrokloried (Vitamiën B6) waarvan die langdurige gebruik in groot dosisse verband hou met die ontwikkeling van pyn, gevoelloosheid, tinteling, swelling of spierswakheid in verskillende dele van die liggaam.

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### **Bioplus Booster Mokka Stroop bevat suiker en versoeters:**

- Sukrose en glukose wat 'n uitwerking op die beheer van u bloedsuiker kan hê as u suikersiekte het.
- As u dokter vir u gesê het dat u 'n onverdraagsaamheid het vir sekere suiker, skakel u dokter voordat u Bioplus Booster Mokka Stroop gebruik.
- Bevat kunsmatige versoeters: Sakkarien natrium 500 1,33 mg/10 ml, Natriumsiklamaat 13,30 mg/10 ml, Dolsweet 16 Dolcre [ADI 450 Versoeter Mengsel] 11,00 mg/10 ml.
- Bevat glukose wat skadelike vir die tande kan wees.

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### **Bioplus Booster Mokka Stroop bevat alkohol:**

- 843 mg alkohol (etanol) in elke dosis eenheid (10 ml). Die hoeveelheid in 10 ml Bioplus Booster Mokka Stroop is gelykstaande aan 2 ml bier of 0,8 ml wyn.
- Die hoeveelheid alkohol sal waarskynlik nie 'n effek op volwassenes hê nie.
- Die alkohol in hierdie gesondheid aanvulling kan die effekte van ander medisyne beïnvloed. Praat met u dokter of apteker as u ander medisyne gebruik.
- Indien u verslaaf is aan alkohol, praat met u dokter of apteker voordat u hierdie medisyne gebruik.

### **Bioplus Stroop Mokka bevat preserveer middels:**

- Metiel parahidroksibensoaat (E218) en Propiel parahidroksibensoaat (E216) wat allergiese reaksies kan veroorsaak (moontlik vertraag).

### **Bioplus Booster Mokka Stroop bevat natrium:**

- Bioplus Booster Oorspronklik bevat minder as 1 mmol natrium (23 mg) per 5 ml, dit wil sê in wese 'natrium vry'.

### **3. Hoe om Bioplus Booster Mokka Stroop te gebruik**

Gebruik altyd Bioplus Booster Mokka Stroop presies soos beskryf in hierdie voubiljet of soos u dokter of apteker of verpleegster u aanbeveel het. Maak seker by u dokter of apteker of verpleegster indien u onseker is.

Die gewone dosis is:

Volwassenes bo 18 jaar: 10 ml of 2 medisyne mates drie keer 'n dag, na etes.

- **Slegs vir af en toe gebruik. Moenie die aanbeveelde dosis oorskry nie.**
- Vir orale gebruik, gebruik onverdund.
- Skud goed voor gebruik.
- 'n Gevarieerde dieet is die mees doeltreffende en veilige manier om goeie voeding, gesondheid, liggaam samestelling sowel as geestelike en fisiese prestasie te bereik.

### **Indien u meer Bioplus Booster Mokka Stroop gebruik as wat u moet (oordosis)**

- Oormatige hoeveelhede kalsium kan lei tot hiperkalsemie. Simptome van hiperkalsemie sluit in anoreksie, naarheid, braking, hardlywigheid, abdominale pyn, spierswakheid, verstandelike versteurings, verhoogde dors, oormatige urinering, verhoogde kalsium in die niere, nierstene, en, in ernstige gevalle, onreëlmatige hartklop en koma.
- By dosisse van meer as 600 mg per dag kan kafeïen angs, vinnige hartklop,

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hartkloppings, slapeloosheid, rusteloosheid, senuweeagtigheid, bewing en hoofpyn veroorsaak.

- Behandeling is simptomaties en ondersteunend.
- In die geval van oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, skakel die naaste hospitaal of gif sentrum.

### **Indien u vergeet om Bioplus Booster Mokka Stroop te gebruik**

Moenie 'n dubbel dosis gebruik om op te maak vir vergete individuele dosisse nie.

### **Indien u die gebruik van Bioplus Booster Mokka Stroop staak**

U kan die gebruik van Bioplus Booster Mokka Stroop enige tyd staak.

Indien u nog vrae het oor die gebruik van Bioplus Booster Mokka Stroop, vra u dokter of apteker.

### **4. Moontlike newe-effekte**

Bioplus Booster Mokka Stroop kan newe-effekte hê.

Nadelige effekte wat met sianokobalamien aangemeld is, sluit in gastro-intestinale verstourings, koors, kouekoors, warm gloed, duiseligheid, malaise, aknee vorm en bulagtige uitbarstings, en bewing. Nie alle newe-effekte aangemeld vir Bioplus Booster Mokka Stroop is ingesluit in hierdie voubiljet nie. Indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl u Bioplus Booster Mokka Stroop gebruik, raadpleeg asseblief u gesondheidsdiensverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van Bioplus Booster Mokka Stroop en lig u dokter onmiddellik in of gaan na die ongevalle eenheid by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- erge uitslag of jeuk,
- floute

Hierdie is almal baie ernstige newe-effekte. As u dit het, het u dalk 'n ernstige reaksie tot Bioplus Booster Mokka Stroop gehad. U benodig dalk dringende mediese aandag of hospitalisasie.

Lig u dokter onmiddellik in of gaan na die ongevalle eenheid by u naaste hospitaal as u enige van die volgende oplet:

- borspyn
- **angina**
- veranderinge in die manier waarop u hart klop, byvoorbeeld, as u agterkom dat dit vinniger klop,
- moeilik om asem te haal



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- tekens van herhalende infeksies soos koors of seer keel,
- minder urine as wat normaal is vir u,
- vergelying van die vel en oë, donker urine en moegheid wat simptome van lewer probleme kan wees.

Hierdie is almal ernstige newe-effekte. U benodig dalk dringende mediese aandag. Lig u dokter in as u enige van die volgende oplet:

### *Newe-effekte met onbekende gereeldheid:*

- gastro-intestinale versteurings
- koors, koue rillings, warm gloed, duiseligheid, algemene ongemak
- vel afwykings
- bewing

Indien u enige newe-effekte oplet wat nie in hierdie voubiljet genoem is nie, lig asseblief u dokter of apteker in.

### **Aanmeld van newe-effekte**

Indien u newe-effekte kry, praat met u dokter, apteker of verpleegster. U kan ook newe-effekte aanmeld direk by SAHPRA via die "6.04 Adverse Drug Reactions Reporting Form", beskikbaar aanlyn onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>.

Deur newe-effekte aan te meld kan u help om meer inligting oor die veiligheid van Bioplus Booster Mokka Stroop te voorsien.

### **5. Hoe om Bioplus Booster Mokka Stroop te bêre**

BÊRE ALLE MEDISYNE BUITE DIE REIK VAN KINDERS.

Bêre in 'n koel, droë plek teen of laer as 25 °C. Beskerm vanaf lig.

Moenie in 'n badkamer bêre nie.

Moenie die produk gebruik na die verval datum aangedui op die verpakking nie.

Handig in alle ongebruikte medisyne by u apteker vir behoorlike wegdoening.

Moenie wegdoen met ongebruikte medisyne in dreine of riool stelsels (bv. toilette) nie.

### **Inhoud van die pak en ander inligting**

#### **Wat Bioplus Booster Mokka Stroop bevat**

Die aktiewe bestanddele is:

<b>Elke 10 ml bevat:</b>	
Kafeïen (watervry)	90 mg
Kalsium glukonaat	300 mg
voorsien Kalsium (elementeel)	27,9 mg
Kalsium sitraat	60 mg
voorsien Kalsium (elementeel)	12,6 mg
Nikotinamied (Vitamien B3)	8 mg

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Tiamien hidrochloried (Vitamien B1)	5,33 mg
Riboflaviën natrium fosfaat (Vitamien B2)	3,67 mg
d-Pantotenol (Vitamien B5)	3,66 mg
Piridoksien hidrochloried (Vitamien B6)	3 mg
Sianokobalamien (Vitamien B12) 0,1 % mannitol	4 µg

Die ander bestanddele is Sukrose, Vloeibare Glukose (43 Neutraal), Natriumchloried BP, Sakkarien Natrium 500, Mannitol (E421) - [Sianokobalamien (Vitamien B12) 0,1 % in mannitol], Natriumsiklamaat

Sitroensuurmonohidraat, Soutsuur 32 % (pH-aanpassing) Etanol 96,5 %, Dolsweet 16 Dolcre - [ADI 450 Versoeter Mengsel],

Metielparahidroksibensoaat (E218), Propielparahidroksibensoaat (E216), Geur Mokka 507282 T, Gesuiwerde Water

### Hoe Bioplus Booster Mokka Stroop lyk en inhoud van die pak

Bioplus Booster Mokka Stroop is 'n helder geel vloeistof met 'n mokka geur in 10 ml sakkies (gelamineerde plastiek/foelie) wat 10 ml stroop bevat en in 30 ml bottels (amber glas) wat 30 ml stroop bevat.

Pak groottes: 10 ml en 30 ml. Nie alle pak groottes mag bemark word nie.

### Houer van Registrasiesertifikaat

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand 1965

Klante Diens: 0860 ADCOCK/23232625

### Laaste hersiening van voubiljet

15 Augustus 2023

### Registrasienommers

Moet nog toegewys word.

31686 09/2023

adcock ingram 

Datum van Goedkeuring: 15 Augustus 2023