

## PROFFESIONAL INFORMATION

**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.**

### **SCHEDULING STATUS:**

**S0**

### **1. NAME OF THE MEDICINE**

#### **BIOPLUS® EFFERVESCENT TABLETS**

Caffeine anhydrous	100 mg
Thiamine hydrochloride	15 mg
providing thiamine (Vitamin B <sub>1</sub> )	11,8 mg
Riboflavin sodium phosphate	20,5 mg
providing riboflavin (Vitamin B <sub>2</sub> )	16,2 mg
providing sodium (elemental)	1,2 mg
Nicotinamide (Vitamin B <sub>3</sub> )	50 mg
Pyridoxine hydrochloride	10 mg
providing pyridoxine (Vitamin B <sub>6</sub> )	8,2 mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	10 µg
Ascorbic acid (Vitamin C)	1000 mg
Calcium pantothenate	25 mg
providing pantothenic acid (Vitamin B <sub>5</sub> )	23,0 mg
providing calcium (elemental)	2,2 mg
Calcium carbonate	227,5 mg
providing calcium (elemental)	90,9 mg
Calcium glycerophosphate	335,1 mg
providing calcium (elemental)	63,7 mg

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Composition**

<b>Each effervescent tablet contains</b>	
Caffeine anhydrous	100 mg
Thiamine hydrochloride	15 mg
providing thiamine (Vitamin B <sub>1</sub> )	11,8 mg
Riboflavin sodium phosphate	20,5 mg
providing riboflavin (Vitamin B <sub>2</sub> )	16,2 mg
providing sodium (elemental)	1,2 mg
Nicotinamide (Vitamin B <sub>3</sub> )	50 mg

## PROFFESIONAL INFORMATION

Pyridoxine hydrochloride providing pyridoxine (Vitamin B <sub>6</sub> )	10 mg 8,2 mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	10 µg
Ascorbic acid (Vitamin C)	1000 mg
Calcium pantothenate providing pantothenic acid (Vitamin B <sub>5</sub> ) providing calcium (elemental)	25 mg 23,0 mg 2,2 mg
Calcium carbonate providing calcium (elemental)	227,5 mg 90,9 mg
Calcium glycerophosphate providing calcium (elemental)	335,1 mg 63,7 mg

### *Excipient(s) with known effect:*

Contains sweeteners: Each tablet contains 17,16 mg sodium saccharin and 24 mg aspartame.

Alcohol and sugar free.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Effervescent tablets.

Pink, round, flat edged effervescent tablets.

After effervescence: clear raspberry red liquid with an odour of tangerine.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

BIOPUS® EFFERVESCENT TABLETS is an effervescent tablet containing caffeine, the B-vitamins and calcium. Caffeine has been known to temporarily 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 also contribute to normal neurotransmission. Calcium contributes to normal muscle function and maintains and promotes the growth of strong bones and teeth.

### 4.2 Posology and method of administration

#### Posology

Adults: Take 1 effervescent tablet daily.

Dissolve the effervescent tablet in a glass of water.

## PROFFESIONAL INFORMATION

### Special Populations

#### Paediatric population

Not suitable for use in children and adolescents under 18 years of age

### Method of administration

For occasional use only. Do not exceed the recommended dosage. Oral use.

### 4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Nicotinamide should not be used in patients with significant hepatic impairment, and other hepato-biliary disorders.
- Cyanocobalamin should not be used in patients with Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.
- Calcium should generally be avoided in patients with calcium renal calculi, or a history of renal calculi.
- Calcium citrate should be avoided in patients with renal failure taking aluminium compounds.

### 4.4 Special warnings and precautions for use

- Increased intake of calcium in patients with hyperthyroidism may result in hypercalcaemia.
- Calcium salts should be given with caution to patients with impaired renal function or a history of renal stone formation.
- The symptoms of subacute degeneration of the spinal cord or pernicious anaemia may be masked by the administration of Cyanocobalamin.
- Large doses of riboflavin result in a bright yellow discolouration of the urine that may interfere with certain laboratory tests.
- Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies.
- Caution is required when using nicotinamide in patients with active peptic ulcer disease or acute coronary syndrome, patients with or predisposed to gout, or in those who consume large amounts of alcohol.
- Patients with diabetes mellitus should be monitored closely when taking nicotinamide as increases in fasting blood glucose have occurred.
- Calcium should be given cautiously to patients with renal impairment, or diseases associated with hypercalcaemia such as sarcoidosis and some malignancies.
- 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
- A cup of instant coffee contains approximately 80 mg of caffeine.

## PROFFESIONAL INFORMATION

- Not suitable for children under the age of 18 years (see section 4.2).
- Total caffeine intake of more than 200 mg per day is not recommended during pregnancy and breastfeeding (see section 4.6).
- Consumption with other medicines (e.g., bitter orange extract, synephrine, octopamine, ephedra, ephedrine) which increase blood pressure is not recommended.
- Use of caffeine may result in sleep deprivation.
- Consumption with other caffeine-containing products or foods (e.g., medications, coffee, tea, colas, cocoa, guarana mate) is not recommended.
- Discontinue use two weeks prior to surgery.
- This medicinal product contains 239,2 mg of sodium per effervescent tablet equivalent to 11,9% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

### **Diabetes:**

BIOPLUS® EFFERVESCENT TABLETS can change blood glucose levels and may interfere with blood glucose control in diabetic patients. Caution is advised in patients with diabetes (see section 4.5).

### **Renal impairment and renal calcium oxalate calculi:**

Calcium is excreted via the kidneys and calcium serum concentrations may be increased in patients with renal impairment. Caution is advised in patients with renal impairment. Large doses of ascorbic acid may increase the formation of renal calcium oxalate calculi.

### **BIOPLUS® EFFERVESCENT TABLETS contains aspartame:**

BIOPLUS® EFFERVESCENT TABLETS contain aspartame. Aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine.

## **4.5 Interaction with other medicines and other forms of interaction**

### **Other medicines:**

- BIOPLUS® EFFERVESCENT TABLETS may decrease the absorption of certain other medicines by the formation of complexes, such as bisphosphonates, fluoride, fluoroquinolones, tetracyclines, dolutegravir, raltegravir, levothyroxine and sotalol. Doses should be separated by at least 2 – 3 hours prior to or after taking BIOPLUS® EFFERVESCENT TABLETS.
- Calcium enhances the effects of digitalis on the heart and may precipitate digitalis intoxication.
- Calcium pantothenate should not be given with or immediately after parasympathomimetic drugs or suxamethonium.

## PROFFESIONAL INFORMATION

### 4.6 Fertility, pregnancy and lactation

Total caffeine intake of more than 200 mg per day is not recommended during pregnancy. Total caffeine intake more than 200 mg per day is not recommended during lactation. No fertility data is available.

### 4.7 Effects on ability to drive and use machines

BIOPLUS® EFFERVESCENT TABLETS have no known effects on the ability to drive and use machines.

### 4.8 Undesirable effects

BIOPLUS® EFFERVESCENT TABLETS is generally well tolerated.

System organ class	Frequency unknown
Immune system disorders	Hypersensitivity (including rash and pruritis)
Nervous system disorders	Headache, dizziness, somnolence, paraesthesia
Vascular disorders	Flushing
Gastrointestinal disorders	Diarrhoea, gastrointestinal discomfort or irritation, nausea, vomiting, constipation, flatulence

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions of BIOPLUS® EFFERVESCENT TABLETS is important. It allows continued monitoring of the benefit/risk balance of BIOPLUS® EFFERVESCENT TABLETS. Health care providers are asked to report any suspected adverse reactions to the Adcock Ingram Pharmacovigilance department by e-mail to [Adcock.Aereports@adcock.com](mailto:Adcock.Aereports@adcock.com), fax to +27 86 553 0128 or call 011 635 0134. Alternatively, it can be reported to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

### 4.9 Overdose

- At doses of more than 600 mg per day, caffeine may cause anxiety, tachycardia (rapid heart rate) palpitations, insomnia, restlessness, nervousness, tremor and

## PROFFESIONAL INFORMATION

headache.

- In overdose, side effects can be precipitated and/or be of increased severity.
- In the event of overdosage, treatment should be symptomatic and supportive.

### 5. PHARMACOLOGICAL PROPERTIES:

Category D: Health Supplements.

34.12 Multiple substance formulation.

Pharmacotherapeutic group: Vitamin B-complex, other combinations

ATC code: A11EX.

#### 5.1 Pharmacodynamic properties

##### Mechanism of action:

**Vitamin C** is essential for the synthesis of collagen and intercellular material.

**Calcium** has a structural role in bones and teeth. Calcium is also essential for cellular structure, blood clotting, muscle contraction, nerve transmission, enzyme activation and hormone function.

**Vitamin B<sub>3</sub>** functions as a component of two coenzymes, nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide diphosphate (NADP). These coenzymes participate in many metabolic processes including glycolysis, tissue respiration, lipid, amino acid and purine metabolism.

**Vitamin B<sub>5</sub>** functions mainly as a component of coenzyme A and acyl carrier protein. Coenzyme A has a central role as a cofactor for enzymes involved in the metabolism of lipids, carbohydrates and proteins; it is also required for the synthesis of cholesterol, steroid hormones, acetylcholine and porphyrins. As a component of acyl carrier protein, pantothenic acid is involved in various transfer reactions and in the assembly of acetate units into longer chain fatty acids.

**Vitamin B<sub>2</sub>** functions as a component of two flavin coenzymes – flavin mononucleotide (FMN) and flavin adenine dinucleotide (FAD). It participates in oxidation–reduction reactions in numerous metabolic pathways and in energy production.

**Vitamin B<sub>1</sub>** functions as a coenzyme in the oxidative decarboxylation of alpha-ketoacids (involved in energy production) and in the transketolase reaction of the pentose phosphate pathway (involved in carbohydrate metabolism). It is also important in nerve transmission (independently of coenzyme function).

**Vitamin B<sub>6</sub>** is converted in erythrocytes to pyridoxal phosphate and, to a lesser extent, pyridoxamine phosphate. It acts as a cofactor for enzymes that are involved in more than 100 reactions affecting protein, lipid and carbohydrate metabolism. Pyridoxal phosphate is also involved in the synthesis of several neurotransmitters; the metabolism of several vitamins (e.g., the conversion of tryptophan to niacin); and haemoglobin and sphingosine formation.

**Vitamin B<sub>12</sub>** is involved in the recycling of folate coenzymes and the degradation of valine. It is also required for nerve myelination, cell replication, haematopoiesis and nucleoprotein synthesis.

**Caffeine** is a methylxanthine that inhibits the enzyme phosphodiesterase and has an

## PROFFESIONAL INFORMATION

antagonistic effect at central adenosine receptors. It is a stimulant of the CNS, particularly the higher centres, and it can produce a condition of wakefulness and increased mental activity. It may also stimulate the respiratory centre, increasing the rate and depth of respiration. Caffeine facilitates the performance of muscular work and increases the total work that can be performed by a muscle.

### 5.2 Pharmacokinetic properties:

**Vitamin C** is a water-soluble vitamin which is readily absorbed from the gastrointestinal tract and is widely distributed in the body. The main route of elimination is through urine.

Calcium is absorbed from the small intestine and the majority of calcium is stored in the bones and teeth. It is mainly excreted through the urine and unabsorbed calcium is eliminated via the faecal route.

**Vitamin B<sub>3</sub>** is water-soluble and well absorbed. It is widely distributed in the body and is excreted mainly via urine.

**Vitamin B<sub>5</sub>** is an essential B vitamin. It is absorbed from the small intestines and widely distributed through the body. About 70 % is excreted unchanged in the urine, and 30 % in the faeces.

**Vitamin B<sub>2</sub>** is a water-soluble vitamin that is readily absorbed from the gastrointestinal tract and is widely distributed in the body. It is excreted in the urine.

**Vitamin B<sub>1</sub>** is a water-soluble B-vitamin and is absorbed by the proximal part of the small intestines. It occurs in the body as the metabolically active form thiamine diphosphate and is excreted in the urine.

**Vitamin B<sub>6</sub>** is a water-soluble vitamin which is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

**Vitamin B<sub>12</sub>** is an essential water-soluble vitamin. It is absorbed in the terminal ileum and is mainly stored in the liver. Vitamin B<sub>12</sub> is excreted via urine, faeces, and bile.

**Caffeine** is absorbed readily after oral doses and is widely distributed throughout the body. It passes readily into the CNS and into saliva. In adults, caffeine is metabolised almost completely in the liver via oxidation, demethylation, and acetylation, and is excreted in the urine as 1-methyluric acid, 1-methylxanthine, 7-methylxanthine, 1,7-dimethylxanthine (paraxanthine), 5-acetylamino-6-formylamino-3-methyluracil (AFMU), and other metabolites with only about 1% unchanged. Hepatic cytochrome P450 isoenzyme CYP1A2 is involved in caffeine enzymatic metabolism. The elimination half-life is about 3 to 7 hours. The metabolism of caffeine has been shown to be dose dependent with clearance decreasing as the dose is increased suggesting saturable metabolism. Four- to five-fold differences in plasma half-lives of caffeine are common among healthy people. The plasma half-life of caffeine is decreased by smoking and by exercise and is increased by liver disease such as cirrhosis and viral hepatitis, and in pregnancy. The plasma half-life of caffeine is not affected by old age or obesity. Drug interactions also affect the pharmacokinetics of caffeine, see section 4.5.

### 5.3 Preclinical safety data

No further information of relevance available.

## PROFFESIONAL INFORMATION

### 6. PHARMACEUTICAL PARTICULARS:

#### 6.1 List of excipients

- Aspartame [E951]
- Citric acid, anhydrous [E330]
- Polyethylene glycol 6000 [E1521]
- Sodium bicarbonate [E500]
- Sodium carbonate [E500]
- Hexacol carmosine supra [E122] (colourant)
- Giravome tangerine permaseal
- Sodium Saccharin [E954]

#### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

24 months.

#### 6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

#### 6.5 Nature and contents of container

BIOPLUS® EFFERVESCENT TABLETS are wrapped in aluminium foil and packed into tubes with a snap-on closure and packed into an outer carton.

Pack sizes: 10, 20s and 30's

#### 6.6 Special precautions for disposal

No special requirements.

### 7. HOLDER OF CERTIFICATE OF REGISTRATION

#### Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand

1685

Customer care: 0860 ADCOCK/232625

### 8. REGISTRATION NUMBER(S)

To be allocated.



## PROFFESIONAL INFORMATION

### 9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Not Applicable.

### 10. DATE OF REVISION OF THE TEXT

05 November 2023

PI 31768 02/2024

adcock ingram 

Date of Approval: 5 November 2023

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

**S0**

### BIOPLUS® EFFERVESCENT TABLETS

<b>Each effervescent tablet contains</b>	
Caffeine anhydrous	100 mg
Thiamine hydrochloride providing thiamine (Vitamin B <sub>1</sub> )	15 mg 11,8 mg
Riboflavin sodium phosphate providing riboflavin (Vitamin B <sub>2</sub> ) providing sodium (elemental)	20,5 mg 16,2 mg 1,2 mg
Nicotinamide (Vitamin B <sub>3</sub> )	50 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B <sub>6</sub> )	10 mg 8,2 mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	10 µg
Ascorbic acid (Vitamin C)	1000 mg
Calcium pantothenate providing pantothenic acid (Vitamin B <sub>5</sub> ) providing calcium (elemental)	25 mg 23,0 mg 2,2 mg
Calcium carbonate providing calcium (elemental)	227,5 mg 90,9 mg
Calcium glycerophosphate providing calcium (elemental)	335,1 mg 63,7 mg

Contains sweeteners: Each tablet contains 17,16 mg sodium saccharin and 24 mg aspartame. Alcohol and sugar free.

#### **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 before you start taking BIOPLUS® EFFERVESCENT TABLETS because it contains important information for you.

BIOPLUS® EFFERVESCENT TABLETS is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOPLUS® EFFERVESCENT TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOPLUS® EFFERVESCENT TABLETS with any other person.

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

- 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® EFFERVESCENT TABLETS is and what it is used for
2. What you need to know before you take BIOPLUS® EFFERVESCENT TABLETS
3. How to take BIOPLUS® EFFERVESCENT TABLETS
4. Possible side effects
5. How to store BIOPLUS® EFFERVESCENT TABLETS
6. Contents of the pack and other information

### 1. What BIOPLUS® EFFERVESCENT TABLETS is and what it is used for

BIOPLUS® EFFERVESCENT TABLETS is an effervescent tablet 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 and maintains and promotes the growth of strong bones and teeth.

### 2. What you need to know before you take BIOPLUS® EFFERVESCENT TABLETS

#### Do not take BIOPLUS® EFFERVESCENT TABLETS:

- If you are allergic to the active ingredients or any of the other ingredients of BIOPLUS® EFFERVESCENT TABLETS (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 kidney stones, or a history of kidney stones.
- If you have kidney stones and are taking aluminium compounds.

### Warning and precautions

#### Take special care with BIOPLUS® EFFERVESCENT TABLETS:

- Large doses of riboflavin sodium phosphate (Vitamin B2) may result in a change of the colour of urine, which may interfere with certain laboratory results.
- long-term use of large doses of pyridoxine hydrochloride (Vitamin B6) is linked with the development of pain, numbness, tingling, swelling, or muscle weakness in different parts of the body.
- If you have an active stomach ulcer or reduced blood flow to the heart, with or prone to gout, or if you consume large amounts of alcohol.
- If you have diabetes mellitus.
- If you have kidney disease, or diseases associated with increased calcium levels.

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

- Increased intake of calcium in patients with hyperthyroidism may result in hypercalcaemia.
- The symptoms of subacute degeneration of the spinal cord or pernicious anaemia may be masked by the administration of cyanocobalamin.
- If you have Lichtheim's disease or pernicious anaemia.
- CONTAINS CAFFEINE; 100 mg per effervescent tablet. A cup of instant coffee contains approximately 80 mg of caffeine.
- Use of caffeine may result in sleep deprivation.
- 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.
- Your body can become tolerant to caffeine. If you suddenly stop taking it, you may experience withdrawal symptoms such as irritability, restlessness, tiredness and headaches.
- Use of caffeine with medicines that increase blood pressure (e.g., bitter orange extract, synephrine, octopamine, ephedra, ephedrine) is not recommended.
- Total caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding. See "pregnancy, breastfeeding and fertility".

### Children and adolescents

Do not use BIOPLUS® EFFERVESCENT TABLETS in children and adolescents under the age of 18 years.

### Other medicines and BIOPLUS® EFFERVESCENT TABLETS

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

- BIOPLUS® EFFERVESCENT TABLETS may decrease the absorption of certain other medicines by the formation of complexes, such as bisphosphonates, fluoride, fluoroquinolones, tetracyclines, dolutegravir, raltegravir, levothyroxine and sotalol. Doses should be separated by at least 2 – 3 hours prior to or after taking BIOPLUS® EFFERVESCENT TABLETS
- Calcium enhances the effects of digitalis on the heart and may precipitate digitalis intoxication.
- Calcium Pantothenate should not be given with or immediately after parasympathomimetic drugs or suxamethonium.

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

### **Pregnancy, breastfeeding and fertility**

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. 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. There is no data available on the effects of BIOPLUS® EFFERVESCENT TABLETS on fertility.

### **Driving and using machines**

The influence of BIOPLUS® EFFERVESCENT TABLETS on the ability to drive and use machines is not known. It is not always possible to predict to what extent BIOPLUS® EFFERVESCENT TABLETS 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® EFFERVESCENT TABLETS affects them.

### **BIOPLUS® EFFERVESCENT TABLETS contains aspartame:**

Each tablet contains 24 mg aspartame. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### **BIOPLUS® EFFERVESCENT TABLETS contains sodium:**

BIOPLUS® EFFERVESCENT TABLETS contains 239,2 mg of sodium (main component of cooking/table salt). In each tablet. This is equivalent to 11,9 % of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to take BIOPLUS® EFFERVESCENT TABLETS**

Always use BIOPLUS® EFFERVESCENT TABLETS 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: Take 1 effervescent tablet daily.

Dissolve the effervescent tablet in a glass of water.

### **For occasional use only. Do not exceed the recommended dosage.**

For oral 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.

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

### **If you take more BIOPLUS® EFFERVESCENT TABLETS than you should**

At doses of more than 600 mg per day, caffeine may cause anxiety, rapid heart rate, palpitations, insomnia, restlessness, nervousness, tremor and headache. In overdose, side effects can be precipitated and/or be of increased severity. In the event of overdose, treatment should be symptomatic and supportive. In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **If you forget to take BIOPLUS® EFFERVESCENT TABLETS**

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

### **If you stop taking BIOPLUS® EFFERVESCENT TABLETS**

You can stop taking BIOPLUS® EFFERVESCENT TABLETS at any time. If you have any further questions on the use of BIOPLUS® EFFERVESCENT TABLETS, ask your doctor or pharmacist.

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

BIOPLUS® EFFERVESCENT TABLETS can have side effects.

Not all side effects reported for BIOPLUS® EFFERVESCENT TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOPLUS® EFFERVESCENT TABLETS, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

- Side effects with unknown frequency:
- Skin rash or itchiness
- Headache, dizziness, drowsiness
- Tingling or numbness of the skin
- Flushing
- Diarrhoea
- Gastrointestinal discomfort or irritation
- Nausea
- Vomiting

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

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

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 BIOPLUS® EFFERVESCENT TABLETS.

### 5. How to store BIOPLUS® EFFERVESCENT TABLETS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in a cool, dry place at or below 25 °C

Protect from light and moisture.

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® EFFERVESCENT TABLETS contains

The active substances are:

Each effervescent tablet contains	
Caffeine anhydrous	100 mg
Thiamine hydrochloride providing thiamine (Vitamin B <sub>1</sub> )	15 mg 11,8 mg
Riboflavin sodium phosphate providing riboflavin (Vitamin B <sub>2</sub> ) providing sodium (elemental)	20,5 mg 16,2 mg 1,2 mg
Nicotinamide (Vitamin B <sub>3</sub> )	50 mg
Pyridoxine hydrochloride providing pyridoxine (Vitamin B <sub>6</sub> )	10 mg 8,2 mg
Cyanocobalamin (Vitamin B <sub>12</sub> )	10 µg
Ascorbic acid (Vitamin C)	1000 mg
Calcium pantothenate providing pantothenic acid (Vitamin B <sub>5</sub> ) providing calcium (elemental)	25 mg 23,0 mg 2,2 mg
Calcium carbonate providing calcium (elemental)	227,5 mg 90,9 mg
Calcium glycerophosphate providing calcium (elemental)	335,1 mg 63,7 mg

The other ingredients are aspartame [E951], citric acid, anhydrous [E330], polyethylene glycol 6000 [E1521], sodium bicarbonate [E500], sodium carbonate [E500], hexacol carmosine supra [E122] (colourant), giravome tangerine permaseal and sodium saccharin [E954]

**Date of Approval: 5 November 2023**

## PATIENT INFORMATION LEAFLET

### **What BIOPLUS® EFFERVESCENT TABLETS looks like and contents of the pack**

BIOPLUS® EFFERVESCENT TABLETS is a pink, round effervescent tablet, which after effervescing in water becomes a clear red solution.

BIOPLUS® EFFERVESCENT TABLETS are wrapped in aluminium foil and packed into tubes with a snap-on closure and packed into an outer carton.

Pack sizes: 10, 20s and 30's. Not all pack sizes may be marketed.

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

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand

1685

0860 ADCOCK/232625

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

05 November 2023

### **Registration number**

To be allocated

31768 02/2024

adcock ingram 

**Date of Approval: 5 November 2023**



## PASIËNT INLIGTING VOUBILJET

### SKEDULERINGSTATUS:

**S0**

### BIOPLUS® BRUISTABLETTE

<b>Elke bruistablet bevat</b>	
Kafeien waterloos	100 mg
Tiamienhidrochloried wat tiamien verskaf (Vitamien B <sub>1</sub> )	15 mg 11,8 mg
Riboflaviën natriumfosfaat wat riboflaviën verskaf (Vitamien B <sub>2</sub> )	20,5 mg 16,2 mg
wat natrium (elementeel) verskaf	1,2 mg
Nikotienamied (Vitamien B <sub>3</sub> )	50 mg
Piredoksienhidrochloried wat piredoksien verskaf (Vitamien B <sub>6</sub> )	10 mg 8,2 mg
Siannokobalamien (Vitamien B <sub>12</sub> )	10 µg
Askorbiensuur (Vitamien C)	1000 mg
Kalsiumpantotenaat wat pantoteensuur verskaf (Vitamien B <sub>5</sub> )	25 mg 23,0 mg
wat kalsium (elementeel) verskaf	2,2 mg
Kalsiumkarbonaat wat kalsium (elementeel) verskaf	227,5 mg 90,9 mg
Kalsiumgliserofosfaat wat kalsium (elementeel) verskaf	335,1 mg 63,7 mg

Bevat versoeters: Elke tablet bevat 17,16 mg natriumsakkarien en 24 mg aspartaam. Alkohol- en suikervry.

### Kategorie D: Aanvullende Medisyne

#### Gesondheidsaanvullings: D34.12 Veelvoudige stowwe formulering

**Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir kwaliteit, veiligheid of beoogde gebruik getoets nie.**

Lees die hele voubiljet voor u BIOPLUS® BRUISTABLETTE begin gebruik want dit bevat belangrike inligting.

BIOPLUS® BRUISTABLETTE is beskikbaar sonder 'n doktersvoorskrif, vir u om u gesondheid te handhaaf. U moet BIOPLUS® BRUISTABLETTE nietemin steeds omsigtig gebruik om die beste resultate daarvan te kry.

- Hou hierdie voubiljet. U mag dit weer moet lees.

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

- Moenie BIOPLUS® BRUISTABLETTE met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgdiensverskaffer of apteker indien u meer inligting of raad nodig.
- U moet 'n dokter raadpleeg as u simptome vererger of nie na 7 dae verbeter nie.

### Wat is in hierdie voubiljet

1. Wat BIOPLUS® BRUISTABLETTE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u BIOPLUS® BRUISTABLETTE begin gebruik
3. Hoe om BIOPLUS® BRUISTABLETTE te gebruik
4. Moontlike nuwe-effekte
5. Hoe om BIOPLUS® BRUISTABLETTE te gebruik
6. Inhoud van die pak en ander inligting

### 1. Wat BIOPLUS® BRUISTABLETTE is en waarvoor dit gebruik word

BIOPLUS® BRUISTABLETTE is 'n bruistablet wat kaffeïen, die B-vitamiene en kalsium bevat. Koffeïen is bekend daarvoor dat dit geestelike waaksaamheid verhoog wat 'n vinniger en helderder denkproses tot gevolg het. Dit verminder verder die gevoel van moegheid en limerigheid wat verbeterde gemoedstoestand tot gevolg het.

Die B-groep Vitamiene help met die metabolisme van vetsure, koolhidrate en proteïene vir die vrystelling en vervaardiging van energie. Hulle is ook betrokke by die onderhoud van 'n gesonde senuweestelsel. Kalsium help ook met spiersaamtrekking en onderhoud en bevorder die groei van sterk bene en tande.

### 2. Wat u moet weet voordat u BIOPLUS® BRUISTABLETTE gebruik

#### Moenie BIOPLUS® BRUISTABLETTE gebruik nie:

- Indien u allergies vir die aktiewe- of enige ander bestanddele van BIOPLUS® BRUISTABLETTE (in afdeling 6 gelys) is nie.
- Indien u lewerversaking, en enige ander verstourings van die galbuis het .
- Indien u genetiese oogsiekte het.
- Indien u nierstene, of 'n geskiedenis van nierstene het.
- Indien u nierstene het en aluminiumverbinding gebruik.

### Waarskuwing en voorsorgmaatreëls

BIOPLUS® BRUISTABLETTE moet omsigtig gebruik word:

- Groot dosisse riboflavin natriumfosfaat (Vitamiene B<sub>2</sub>) kan 'n verandering in die kleur van urine tot gevolg hê, wat met sekere laboratoriumuitslae kan inmeng.
- Lang-termyn gebruik van groot dosisse piroksienhidrochloried (Vitamiene B<sub>6</sub>) word aan die ontwikkeling van pyn, gevoelloosheid, tinteling, swelling, of spierswakheid in verskillende dele van die liggaam.
- Indien u 'n aktiewe maagsweer of verminderde bloedvloei na die hart het, of geneig is om jigg te ondervind, of indien u groot hoeveelhede alkohol gebruik.

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

- Indien u diabetes mellitus het.
- Indien u niersiekte of siektes wat met verhoogde kalsiumvlakke gepaard gaan, het.
- Verhoogde inname van kalsium by pasiënte met hiperteriose kan hiperkalsemie tot gevolg hê.
- Die toediening van sianokobalamien kan die simptome van subakute degenerasie van die rugmurg of pernisiëuse anemie maskeer.
- Indien u Lichtheim se siekte of pernisiëuse anemie het.
- BEVAT KAFFEÏNE; 100 mg per bruistablet. 'n Koppie kitskoffie bevat ongeveer 80 mg kaffeïen.
- Die gebruik van kaffeïen kan slaapgebrek tot gevolg hê.
- Raadpleeg 'n geregistreerde gesondheidsorgwerker indien u enige ander medisyne (soos litium) gebruik, wat chroniese-, aanvullende-, of tradisionele medisyne insluit; of hoë bloeddruk, gloukoom, en/of ooraktiewe blaas-sindroom het.
- Gebruik van ander kaffeïenbevattende produkte of voedsel (bv. medikasie, koffie, tee, kolas, kakao, guarana maté) word nie aanbeveel nie.
- Staak gebruik twee weke voor chirurgie.
- U liggaam kan verdraagsaamheid vir kaffeïen ontwikkel. Indien u skielik ophou om dit te neem, mag u onttrekkingsimptome soos prikkelbaarheid, rusteloosheid, moegheid en hoofpyn ervaar.
- Gebruik van kaffeïen tesame met medisyne wat bloeddruk verhoog (bv. bitterlemoenaftreksel, sinefrien, oktopamien, efedra, efedrien) word nie aanbeveel nie.
- Totale kaffeïeninname van meer as 200 mg per dag word nie tydens swangerskap of borsvoeding aanbeveel nie. Sien "Swangerskap, borsvoeding en vrugbaarheid".

### **Kinders en adolessente**

Moenie BIOPLUS® BRUISTABLETTE vir kinders en adolessente onder die ouderdom van 18 jaar oud gebruik nie.

### **Ander medisyne en BIOPLUS® BRUISTABLETTE**

Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne gebruik. (Dit sluit aanvullende- en tradisionele medisynes in.)

- BIOPLUS® BRUISTABLETTE kan die opname van sekere ander medisynes verminder wanneer komplekse, soos bisfonate, fluoried, fluorokinolone, tetrasikliene, dolutegravir, taltegravir, levotiroksien en sotaloll vorm. Dosisse moet ten minste 2 – 3 ure voor of na die neem van BIOPLUS® BRUISTABLETTE geneem word.
- Kalsium versterk die invloed van digitalis op die hart en kan digitalisvergiftiging presipiteer.
- Kalsiumpantotenaat moenie direk na parasimptomatiese middels of susametonium gegee word nie.

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

### **Swangerskap, borsvoeding en vrugbaarheid**

Moeders moet hulle inname van kaffeïen goed dophou. Kaffeïen gaan deur die menslike plasenta, maar is nie 'n faktor wat die misvorming van 'n embrio veroorsaak nie. Kaffeïen bereik 'n hoogtepunt ongeveer 1-2 ure na inname by die moeder. Indien u van vrugbare ouderdom is, swanger is of borsvoed en u is bekommerd dat u daaglikse kaffeïeninname uit alle bronne meer as 200 mg per dag kan oorskry, raadpleeg asseblief 'n toepaslike gesondheidsorgverskaffer voor gebruik. Indien u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie gesondheidsaanvulling gebruik. Daar is geen data beskikbaar oor die uitwerking van BIOPLUS® BRUISTABLETTE op vrugbaarheid nie.

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

Die invloed van BIOPLUS® BRUISTABLETTE op die vermoë om te bestuur of masjinerie te bedryf is nie bekend nie. Dit is nie altyd moontlik om te voorspel tot watter mate BIOPLUS® BRUISTABLETTE kan inmeng met daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet verseker dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle bewus is tot watter mate BIOPLUS® BRUISTABLETTE hulle affekteer nie.

### **BIOPLUS® BRUISTABLETTE bevat aspartaam:**

Elke tablet bevat 24 mg aspartaam. Aspartaam is 'n bron van fenielalanien. Dit kan skadelik wees as u fenielketonurie (FKU), 'n skaars genetiese toestand waar fenielalanien opbou omdat die liggaam dit nie behoorlik kan verwyder nie.

### **BIOPLUS® BRUISTABLETTE bevat natrium:**

BIOPLUS® BRUISTABLETTE bevat 239,2 mg natrium (hoofbestanddeel van kook/tafelsout) in elke tablet. Dit is gelykstaande aan 11,9 % van die aanbevole maksimum daaglikse dieetinname van natrium vir 'n volwassene.

### **3. Hoe om BIOPLUS® BRUISTABLETTE te gebruik**

Gebruik BIOPLUS® BRUISTABLETTE altyd presies soos dit in die voubiljet of soos deur u dokter, apteker of verpleegster voorgeskryf is. Bevestig met u dokter, apteker of verpleegster indien u onseker is.

Die gewone dosis is:

Volwassenes: Neem 1 bruistablet daaglik.

Los die bruistablet in 'n glas water op.

### **Slegs vir af en toe gebruik. Moenie die aanbevole dosis oorskry nie.**

Vir mondelikse gebruik.

'n Gevarieerde dieet is die mees effektiewe en veilige manier om goeie voeding, gesondheid,

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

liggaamsamestelling sowel as geestelike en fisiese prestasie te bereik.

### **Indien u meer BIOPLUS® BRUISTABLETTE neem as wat u moet**

Kaffeïen kan met dosisse van meer as 600 mg per dag angstigheid, vinnige hartklop, hartkloppings, slapeloosheid, rusteloosheid, senuweeagtigheid, bewing en hoofpyn veroorsaak. Nuwe-effekte kan met oordosering presipiteer en/of vererger. Behandeling in die geval van oordosering moet simptome en ondersteunend wees. Raadpleeg u dokter of apteker in geval van oordosering. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

### **Indien u vergeet om BIOPLUS® BRUISTABLETTE te neem**

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

### **Indien u ophou om BIOPLUS® BRUISTABLETTE te neem**

U kan ter enige tyd gebruik van BIOPLUS® BRUISTABLETTE staak. Vra u dokter of apteker indien u enige verdere vra oor die gebruik van BIOPLUS® BRUISTABLETTE het.

## **4. Moontlike nuwe-effekte**

BIOPLUS® BRUISTABLETTE kan nuwe-effekte hê.

Nie alle nuwe-effekte aangemeld vir BIOPLUS® BRUISTABLETTE is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid versleg of as u enige ongewenste effekte ervaar terwyl u BIOPLUS® BRUISTABLETTE gebruik, raadpleeg asseblief u gesondheidsdiensverskaffer vir advies.

Vertel u dokter as u enige van die volgende opmerk:

- Nuwe-effekte van onbekende oorsaak:
- Veluitslag of jeuking
- Hoofpyn, duiseligheid of lomerigheid
- Tinteling of gevoelloosheid van die vel
- Gloede
- Diarree
- Gastroïntestinale ongemak of irritasie
- Naarheid
- Braking

Stel u dokter of apteker in kennis indien u enige nuwe-effekte opmerk wat nie in hierdie voubiljet genoem word nie.

### **Aanmeld van nuwe-effekte**

Indien u nuwe-effekte ervaar, praat met u dokter of apteker. U kan ook nuwe-effekte aanmeld

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

by SAHPRA via die “6.04 Adverse Drug Reaction Reporting Form”, aanlyn beskikbaar 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 voorsien oor die veiligheid van BIOPLUS® BRUISTABLETTE.

### 5. Hoe om BIOPLUS® BRUISTABLETTE te bêre

BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

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

Beskerm teen lig en vog.

Moenie in 'n badkamer bêre nie.

Moenie na die vervaldatum wat op die verpakking gemeld word gebruik nie.

Gee alle ongebruikte medisyne aan u apteker terug vir behoorlike wegdoening.

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

### 6. Inhoud van pak en ander inligting

Wat BIOPLUS® BRUISTABLETTE bevat

Die aktiewe bestanddele is:

Each effervescent tablet contains	
Kafeïen waterloos	100 mg
Tiamienhidrochloried wat tiamien verskaf (Vitamien B <sub>1</sub> )	15 mg 11,8 mg
Riboflaviën natriumfosfaat wat riboflaviën verskaf (Vitamien B <sub>2</sub> )	20,5 mg 16,2 mg
wat natrium (elementeel) verskaf	1,2 mg
Nikotienamied (Vitamien B <sub>3</sub> )	50 mg
Piredoksienhidrochloried	10 mg
wat piredoksien verskaf (Vitamien B <sub>6</sub> )	8,2 mg
Siannokobalamien (Vitamien B <sub>12</sub> )	10 µg
Askorbiensuur (Vitamien C)	1000 mg
Kalsiumpantotenaat	25 mg
wat pantoteensuur verskaf (Vitamien B <sub>5</sub> )	23,0 mg
wat kalsium (elementeel) verskaf	2,2 mg
Kalsiumkarbonaat	227,5 mg
wat kalsium (elementeel) verskaf	90,9 mg
Kalsiumgliserofosfaat	335,1 mg
wat kalsium (elementeel) verskaf	63,7 mg

Die ander bestanddele is aspartaam [E951], sitroensuur, waterloos [E330], poliëtileenglikol

**Date of Approval: 5 November 2023**

## PASIËNT INLIGTING VOUBILJET

6000 [E1521], natriumbikarbonaat [E500], natriumkarbonaat [E500], heksakoolkarmosiensupra [E122] (kleurmiddel), *giravome tangerine permaseal* en natriumsakkarien [E954]

### Hoe BIOPLUS® BRUISTABLETTE lyk en inhoud van pak

BIOPLUS® BRUISTABLETTE is 'n pienk, ronde bruistablet, wat na opbruising 'n deurskynende rooi oplossing word.

BIOPLUS® BRUISTABLETTE is in aluminiumfoelie toegedraai en in buise met 'n aanknipprop verpak, wat in 'n buitenste dosie verpak is.

Pakgroottes: 10, 20 en 30. Nie alle pakgroottes word noodwendig bemark nie.

### Houer van Sertifikaat van Registrasie

Adcock Ingram Beperk

1 New Road

Erand Gardens

Midrand

1685

0860 ADCOCK/232625

### Laaste hersiening van voubiljet

05 November 2023

### Registrasienuommer

Nog nie toegeken nie

31768 02/2024

adcock ingram 

Date of Approval: 5 November 2023