Category D: Complementary Medicine

Health Supplements: D 34.12 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 Syrup

Multiple Substance Formulation, syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml contains:	
Caffeine	90,0 mg
Calcium gluconate providing Calcium (elemental)	300,0 mg 27,3 mg
Calcium citrate providing Calcium (elemental)	55,6 mg 14,5 mg
Nicotinamide (Vitamin B_3)	14,0 mg
Thiamine hydrochloride providing Thiamine (Vitamin B_1)	5,3 mg 4,2 mg
Riboflavin sodium phosphate providing Riboflavin (Vitamin B_2)	4,0 mg 3,7 mg
d-Pantothenol providing d-Pantothenic acid (Vitamin B_5)	3,7 mg 3,4 mg
Pyridoxine hydrochloride providing Pyridoxine (Vitamin B_6)	3,0 mg 2,5 mg
Cyanocobalamin (Vitamin B_{12})	8,7 µg

Preservatives:

Methyl parahydroxybenzoate 0,09 % *m/v*

Propyl parahydroxybenzoate 0,01 % *m/v*

Contains sugar: Mannitol 17,32 mg, Sucrose 2,4 g and Glucose 1,3 g per 10 ml.

Contains artificial sweetener: Saccharin sodium 1,3 mg and Sodium cyclamate 13,3 mg per 10 ml.

Contains alcohol 10,0 % *v/v*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

A clear red liquid with a cherry-brandy flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Bioplus Syrup is a tonic that assists with increase in mental alertness resulting in a rapid and clearer flow of thought. It assists with reduction of feelings of fatigue and drowsiness resulting in an enhanced state of mind.

4.2 Posology and method of administration

Posology

Adults over 18 years of age: Take 2 medicine measures (or 10 ml) three times a day.

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.

For oral use.

Bioplus Syrup should be taken undiluted.

Shake the bottle before use.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Concomitant use with digitalis, e.g. digoxin (see section 4.5)
- Children under the age of 18 years.

4.4 Special warnings and precautions for use

- Hypersensitivity/allergy reaction may occur, in which case, use should be discontinued.
- **Bioplus Syrup** CONTAINS CAFFEINE.
  - Each dosage unit (10 ml) of syrup contains 90 mg of caffeine. A cup of instant coffee contains approximately 80 mg of caffeine.

- Exercise care in patients taking any other medicine (such as lithium) including chronic, complementary, or traditional medicines; or have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome).
- Individuals of childbearing age, who are pregnant or lactating and have concerns that their daily intake of caffeine from all sources may exceed 200 mg per day, should be advised to consult a relevant healthcare provider prior to use (see section 4.6).
- Use of caffeine may result in sleep deprivation.
- Use should be discontinued two weeks prior to surgery.

- **Bioplus Syrup** contains:
    - **Sugars (sucrose** and **glucose),** which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with rare glucose-galactose malabsorption should not take **Bioplus Syrup**. Sucrose and glucose may be harmful to the teeth.
    - **Ethanol (alcohol)** 843 mg in each dosage unit (10 ml) which is equivalent to 0,843 g/10ml or 8,43 % *w/v*. The amount in 10 ml of **Bioplus Syrup** is equivalent to 2 ml of beer or 0,8 ml of wine. The small amount of alcohol in **Bioplus Syrup** will not have any noticeable effects.
    - **Methyl parahydroxybenzoate (E218)** and **propyl parahydroxybenzoate(E216)** which may cause allergic reactions (possibly delayed).
    - **Sodium**14,7 mg sodium per 10 ml, that is to say essentially 'sodium free'.
    - **Azorubine (E122)** and **carmosine (E122)** which may cause allergic reactions.
    - **Propylene glycol** 15 mg in each dosage unit which is equivalent to 15 mg/10 ml.

4.5 Interaction with other medicines and other forms of interaction

- Calcium (as in **Bioplus Syrup**) can enhance the effects of digitalis on the heart and may precipitate digitalis (e.g. digoxin) toxicity. **Bioplus Syrup** should not be taken together with digitalis medicine (see section 4.3).
- Calcium (as in **Bioplus Syrup**) may decrease the absorption of tetracycline (e.g. minocycline) and quinolone (e.g. ciprofloxacin) antibiotics. Doses should be separated by at least 2 hours prior to, or 4 to 6 hours after taking **Bioplus Syrup**.
- Consumption of caffeine (as in **Bioplus Syrup**) with other medicines (e.g. bitter orange extract, synephrine, octopamine, ephedra, ephedrine) which increase blood pressure or other caffeine-containing products or foods (e.g., medications, coffee, tea, colas, cocoa, guarana mate) is not recommended.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Total caffeine (as in **Bioplus Syrup**) intake of more than 200 mg per day is not recommended during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Bioplus Syrup has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a) Summary of the safety profile

Bioplus Syrup is generally well tolerated.

b) Tabulated list of adverse reactions

SYSTEM ORGAN CLASS	*FREQUENCY*	*ADVERSE REACTIONS*
Immune system disorders	Less frequent	allergic reactions
Nervous system disorders	Less frequent	insomnia
Gastrointestinal disorders	Less frequent	constipation

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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 headache.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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ATC code: A11A Multivitamin, combinations

Bioplus Syrup is a multi-vitamin/mineral supplement containing a combination of B-Vitamins which help to metabolise carbohydrates, fats and proteins, thereby contributing to energy-yielding metabolism and reduction of tiredness and fatigue. B-Vitamins are also involved in the maintenance of a healthy nervous system.
Calcium contributes to normal energy-yielding metabolism and normal muscle function.
Cyanocobalamin contributes to normal red blood cell formation.
d-Pantothenic acid contributes to normal mental performance.
Caffeine temporarily promotes alertness and wakefulness, temporarily assists to relieve fatigue and to increase mental activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Liquid glucose
Sodium chloride
Saccharin sodium
Mannitol
Sodium cyclamate
Citric acid monohydrate
Hydrochloric acid (pH adjustment)
Ethanol
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Cherry Brandy Liquid Flavour G2292 (containing propylene glycol, water and azorubine (E122))
Colour Raspberry Red H1277 (containing carmoisine (E122) and icing sugar)
Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light. Keep the container tightly closed.

6.5 Nature and contents of container

An amber glass bottle containing 100 ml, 200 ml or 500 ml of syrup, fitted with a white screw-on closure and packed in a unit carton.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand
1685
Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

22 July 2024

adcock ingram

PI 31960 08/2024