SCHEDULING STATUS: S0

BIOPLUS SYRUP

Multiple ingredient formulation syrup

Caffeine 90,0 mg, Calcium 41,8 mg, Vitamin B_3 14,0 mg, Vitamin B_1 4,2 mg, Vitamin B_2 3,7 mg, Vitamin B_5 3,4 mg, Vitamin B_6 2,5 mg, Vitamin B_{12} 8,7 µg

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

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

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.

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **Bioplus Syrup** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What **Bioplus Syrup** is and what it is used for
2. What you need to know before you take **Bioplus Syrup**
3. How to take **Bioplus Syrup**
4. Possible side effects
5. How to store **Bioplus Syrup**
6. Contents of the pack and other information

1. What Bioplus Syrup is and what it is used for

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.

2. What you need to know before you take Bioplus Syrup

Do not take Bioplus Syrup:

- If you are hypersensitive (allergic) to any of the active ingredients or any of the other ingredients (listed in section 6).
- If you take digitalis medicine, used to treat heart failure, e.g. digoxin.
- If you are younger than 18 years of age.

Warnings and precautions

Take special care with **Bioplus Syrup**:

- If you experience hypersensitivity or allergic reaction, stop using **Bioplus Syrup** and consult a healthcare provider.
- **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.
  - Consult a registered healthcare professional prior to use if you:
    - are 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).
    - 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.
  - Discontinue use two weeks prior to having an operation (surgery).
  - Use of caffeine may result in sleep deprivation.

Other medicines and Bioplus Syrup

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

Tell your doctor or pharmacist if you are currently taking:

- Digitalis medicine (e.g. digoxin), used to treat heart failure, as calcium (as in **Bioplus Syrup**) can intensify its effects on the heart. **Bioplus Syrup** should not be taken together with digitalis medicine.
- Tetracycline or quinolone antibiotic medicines (e.g. ciprofloxacin, minocycline), used to treat bacterial infections, as calcium (as in **Bioplus Syrup**) may decrease their effectiveness. Take antibiotic medicine 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.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before taking **Bioplus Syrup**.

Safety in pregnancy, lactation and fertility has not been established.

Bioplus Syrup contains alcohol which may be harmful during pregnancy and breastfeeding.

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

Driving and using machines

It is not always possible to predict to what extent **Bioplus Syrup** may interfere with your daily activities. Ensure that you do not engage in the above activities until you are aware of the measure to which **Bioplus Syrup** affects them.

Bioplus Syrup contains:

- **Sugars (sucrose** and **glucose)** which may affect the control of your sugar level 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 Syrup**. Sucrose and glucose may be harmful to the teeth.
- **Methyl parahydroxybenzoate (E218)** and **propyl parahydroxybenzoate (E216)** which may cause allergic reactions (possibly delayed).
- **Less than 1 mmol sodium** (23 mg) per dosage unit (10 ml), that is to say essentially ‘sodium-free’.
- **Ethanol (alcohol)** 8,43 % *w/v*, i.e. up to 843 mg per dosage unit (10 ml), equivalent to 2 ml of beer or 0,8 ml of wine, which may be harmful if you are suffering from alcoholism. The small amount of alcohol in **Bioplus Syrup** will not have any noticeable effects.
- **Propylene glycol** 15 mg per 10 ml which is equivalent to 86,5 % *m/m.*
- **Azorubine (E122)** and **carmosine (E122)** which may cause allergic reactions.

3. How to take Bioplus Syrup

Do not share medicines prescribed for you with any other person.
Always use **Bioplus 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: Take 2 medicine measures (10 ml) three times a day.

- For occasional use only. Do not exceed the recommended dosage.
- For oral use, take undiluted.
- Shake the bottle 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 Syrup than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.
At doses of more than 600 mg per day, caffeine may cause nervousness, a forceful heartbeat that may be rapid or irregular, difficulty sleeping, restlessness, shaking, and headache.

If you forget to take Bioplus Syrup

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

4. Possible side effects

Bioplus Syrup can have side effects. **Bioplus Syrup is** generally well tolerated.
Not all side effects reported for **Bioplus Syrup** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Bioplus Syrup**, please consult your healthcare provider for advice.

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

- swelling of lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching and/or hives or fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to **Bioplus Syrup**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- a change in your sleep habits.
- constipation

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store Bioplus Syrup

Store all medicines out of reach of children.

Store at or below 25 ºC. Protect from light.

Keep the container tightly closed.

Do not store in a bathroom.

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

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What Bioplus Syrup contains:

The active substances are:

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

The other ingredients are Cherry brandy liquid flavour (G2292) (containing azorubine (E122), propylene glycol and water), citric acid monohydrate, colour raspberry red (H1277) (containing carmoisine (E122) and icing sugar), ethanol, hydrochloric acid (pH adjustment), liquid glucose, mannitol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water, saccharin sodium, sodium chloride, sodium cyclamate and sucrose.

Contains alcohol 10,0 % *v/v*
Preservatives:
Methyl parahydroxybenzoate 0,09 % *m/v*
Propyl parahydroxybenzoate 0,01 % *m/v*

What Bioplus Syrup looks like and contents of the pack
A clear red liquid with a cherry-brandy flavour.
Packed in 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.

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To be allocated.

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SKEDULERINGSTATUS: S0

BIOPLUS SYRUP

Veelvoudige bestanddeel-formulering stroop

Kaffeïen 90,0 mg, Kalsium 41,8 mg, Vitamien B_3 14,0 mg, Vitamien B_1 4,2 mg, Vitamien B_2 3,7 mg, Vitamien B_5 3,4 mg, Vitamien B_6 2,5 mg, Vitamien B_{12} 8,7 µg
Bevat suiker: Mannitol 17,32 mg, Sukrose 2,4 g en Glukose 1,3 g per 10 ml
Bevat versoeter: Natriumsakkarien 1,3 mg, Natriumsiklamaat 13,3 mg per 10 ml.

Kategorie D: Komplementêre Medisyne
Gesondheidsaanvulling: D 34.12 Veelvoudige bestanddeel formulering

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

Lees die hele voubiljet noukeurig deur, want dit bevat belangrike inligting.
Bioplus Syrup is beskikbaar sonder ŉ doktersvoorskrif om u gesondheid te onderhou.
U moet **Bioplus Syrup** nietemin steeds omsigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Moenie **Bioplus Syrup** met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.

Wat in hierdie voubiljet is

1. Wat **Bioplus Syrup** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **Bioplus Syrup** gebruik
3. Hoe om **Bioplus Syrup** te gebruik
4. Moontlike newe-effekte
5. Hoe om **Bioplus Syrup** te bêre
6. Inhoud van die pak en ander inligting

1. Wat Bioplus Syrup is en waarvoor dit gebruik word

Bioplus Syrup is ŉ tonikum wat help met verhoogde verstandelike wakkerheid wat lei tot vinnige en helder gedagtevloei. Dit help om gevoel van moegheid en lomerigheid te verminder wat ŉ verbeterde gemoedstoestand tot gevolg het.

2. Wat u moet weet voordat u Bioplus Syrup gebruik

Moenie Bioplus Syrup gebruik nie:

- As u hipersensitief (allergies) vir enige van die aktiewe bestanddele of enige van die ander bestanddele is (in afdeling 6 gelys).
- As u digitalis medisyne gebruik vir die behandeling van hartversaking, bv. digoksien.
- As u jonger is as 18 jaar.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met **Bioplus Syrup**:

- Staak gebruik van **Bioplus Syrup** en raadpleeg ŉ gesondheidsorgverskaffer as u hipersensitiwiteit of ŉ allergiese reaksie ervaar.
- **Bioplus Syrup** BEVAT KAFFEÏEN.
  - Elke dosiseenheid (10 ml) stroop bevat 90 mg kaffeïen. ŉ Koppie kitskoffie bevat ongeveer 80 mg kaffeïen.
  - Raadpleeg ŉ geregistreerde gesondheidsorgverskaffer voor gebruik as u:
    - enige ander medisyne (soos litium) gebruik, insluitend chroniese, komplementêre of tradisionele medisyne; of
    - lei aan hoë bloeddruk, gloukoom, en/of detrusor onstabiliteit (ooraktiewe blaas-sindroom); of
    - steeds vrugbaar is, swanger is of borsvoed en u is bekommerd dat die daaglikse inname van kaffeïen van al die bronne 200 mg per dag kan oorskry.
  - Staak gebruik vir twee weke voor u ŉ operasie (sjirurgie) moet ondergaan.
  - Gebruik van kaffeïen kan tot slaapgebrek lei.

Ander medisyne en Bioplus Syrup

Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisynes in.)

Vertel u dokter of apteker as u tans die volgende gebruik:

- Digitalis medisyne (bv. digoksien), wat gebruik word om hartversaking te behandel, want kalsium (soos in **Bioplus Syrup**) kan die uitwerking daarvan op die hart verhoog. **Bioplus Syrup** moenie saam met digitalis medisyne gebruik word nie.
- Tetrasiklien of kinoloon antibiotiese medisynes (bv. siprofloksasien, minosiklien), wat gebruik word om bakteriële infeksies te behandel, want kalsium (soos in **Bioplus Syrup**) kan hulle doeltreffendheid verminder. Neem antibiotiese medisyne ten minste 2 ure voor, of 4 tot 6 ure na gebruik van **Bioplus Syrup**.
- Inname van kaffeïen (soos in **Bioplus Syrup**) saam met ander medisyne (bv. bitterlemoenekstrak, sinefrien, oktopamien, efedra, efedrien) wat bloeddruk verhoog, of ander kaffeïen-bevattende produkte of voedsel (bv. medisynes, koffie, tee, kola,

kakao, guarana-drankies) word nie aanbeveel nie.

Swangerskap, borsvoeding en vrugbaarheid

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer indien u swanger is of borsvoed, dink u kan dalk swanger wees of beplan om 'n baba te hê, voor u **Bioplus Syrup** gebruik.

Veiligheid met swangerskap, laktasie en vrugbaarheid is nog nie vasgestel nie.

Bioplus Syrup bevat alkohol wat skadelik kan wees tydens swangerskap en borsvoeding.

Totale kaffeïen-inname (soos in **Bioplus Syrup**) van meer as 200 mg per dag word nie tydens swangerskap en borsvoeding aanbeveel nie.

Bestuur en hantering van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate **Bioplus Syrup** met u daaglikse aktiwiteite kan inmeng nie. Maak seker dat u nie aan enige van die bogenoemde aktiwiteite deelneem totdat u bewus is van die mate waartoe gebruik van **Bioplus Syrup** dit beïnvloed nie.

Bioplus Syrup bevat:

- **Suikers (sukrose** en **glukose)** wat die beheer van u suikervlakke kan beïnvloed indien u aan diabetes mellitus lei. Indien u dokter u ingelig het dat u 'n intoleransie vir sommige suikers het, kontak hom/haar voordat u **Bioplus Syrup** gebruik. Sukrose en glukose kan skadelik wees vir die tande.
- **Metielparahidroksiebensoaat (E218)** en **propielparahidroksiebensoaat (E216)** wat allergiese reaksies kan veroorsaak (mag moontlik vertraag wees).
- **Minder as 1 mmol natrium** (23 mg) per dosiseenheid (10 ml), wat so te sê essensieel 'natrium-vry' is.
- **Etanol (alkohol)** 8,43 % *m/v*, d.i. tot en met 843 mg per dosiseenheid (10 ml), gelykstaande aan 2 ml bier of 0,8 ml wyn, wat skadelik kan wees indien u aan alkoholisme lei. Die klein hoeveelheid alkohol in **Bioplus Syrup** sal nie enige merkbare invloed hê nie.
- **Propileenglikol** 15 mg per 10 ml wat gelykstaande is aan 86,5 % *m/m.*
- **Asorubien (E122)** en **karmosien (E122)** wat allergiese reaksies kan veroorsaak.

3. Hoe om Bioplus Syrup te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Gebruik **Bioplus Syrup** altyd presies soos in hierdie voubiljet of deur u dokter of apteker of verpleër voorgeskryf is. Bevestig met u dokter of apteker of verpleër indien u onseker is.

Die gewone dosis is:

Volwassenes ouer as 18 jaar: Neem 2 medisyne mates (10 ml) drie keer 'n dag.

- Vir gebruik per geleentheid alleenlik. Moenie nie die aanbevole dosis oorskry nie.
- Vir mondelikse gebruik, neem onverdun.
- Skud die bottel voor gebruik.
- ʼn Gebalanseerde dieet is die mees effektiewe en veilige manier om goeie voeding, gesondheid, liggaamssamestelling asook verstandelike en fisiese prestasie te bereik.

Indien u meer Bioplus Syrup gebruik as wat u moes

Raadpleeg u dokter of apteker in geval van oordosering. Kontak die naaste hospitaal of gifhulpsentrum as nie een van hulle beskikbaar is nie.

Teen dosisse van meer as 600 mg per dag kan kaffeïen senuweeagtigheid, ʼn kragtige hartklop wat vinnig of ongereeld kan wees, moeite om te slaap, rusteloosheid, bewerasie en hoofpyn veroorsaak.

Indien u vergeet om Bioplus Syrup te gebruik

Moenie ʼn dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte

Bioplus Syrup kan newe-effekte hê. **Bioplus Syrup** word oor die algemeen goed verdra. Nie alle newe-effekte wat vir **Bioplus Syrup** aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies indien u algemene gesondheid verswak of indien u enige nadelige gevolge tydens gebruik van **Bioplus Syrup** ervaar.

Staak gebruik van **Bioplus Syrup** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by naaste hospitaal indien enige van die volgende gebeur:

- swelling van lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag of jeukerigheid en/of galbulte of floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar mag u dalk ʼn ernstige allergiese reaksie vir **Bioplus Syrup** gehad het. U mag dringende mediese sorg of hospitalisasie nodig hê.

Vertel u dokter as u enige van die volgende opmerk:

<u>Minder algemene newe-effekte:</u>

- ʼn verandering in u slaapgewoontes
- hardlywigheid

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

Aanmelding van newe-effekte

Raadpleeg u dokter, apteker of verpleër indien u enige newe-effekte ervaar. U kan newe-effekte ook direk by SAHPRA aanmeld via die Med Safety TOEP (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op die SAHPRA webwerf gevind kan word. Deur newe-effekte aan te meld kan u help met om meer inligting te verskaf oor die veiligheid van **Bioplus Syrup**.

5. Hoe om Bioplus Syrup te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 25 ºC. Beskerm teen lig.

Hou die houer dig toe.

Moenie in ŉ badkamer bêre nie.

Moenie na die vervaldatum gebruik wat op die verpakking aangedui is nie.

Neem alle ongebruikte medisyne na u apteker terug.

Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die pak en ander inligting

Wat Bioplus Syrup bevat:

Die aktiewe bestanddele is:

Elke 10 ml bevat:	
Kaffeïen	90,0 mg
Kalsiumglukonaat verskaf Kalsium (elementeel)	300,0 mg 27,3 mg
Kalsiumsitraat verskaf Kalsium (elementeel)	55,6 mg 14,5 mg
Nikotienamied (Vitamien B_3)	14,0 mg
Tiamienhidrochloried verskaf Tiamien (Vitamien B_1)	5,3 mg 4,2 mg
Riboflavien natriumfosfaat verskaf Riboflavien (Vitamien B_2)	4,0 mg 3,7 mg
d-Pantotenol verskaf d-Pantoteniese suur (Vitamien B_5)	3,7 mg 3,4 mg
Piridoksienhidrochloried verskaf Piridoksien (Vitamien B_6)	3,0 mg 2,5 mg
Sianokobalamien (Vitamien B_{12})	8,7 µg

Die ander bestanddele is Kersiebrandewyn vloeibare geursel (G2292) (bevat asorubien (E122), propileenglikol en water), sitroensuurmonohidraat, framboos rooi kleursel (H1277) (bevat karmosien (E122) en versiersuiker), etanol, soutsuur (pH-aanpassing), vloeibare glukose, mannitol, metielparahidroksiebensoaat (E218), propielparahidroksiebensoaat (E216), gesuiwerde water, natriumsakkarien, natriumchloried, natriumsiklamaat en sukrose.

Bevat alkohol 10,0 % *v/v*
Preserveermiddels:
Metielparahidroksiebensoaat 0,09 % *m/v*
Propielparahidroksiebensoaat 0,01 % *m/v*

Hoe Bioplus Syrup lyk en inhoud van pak

ʼn Deurskynende, rooi vloeistof met ʼn kersiebrandewyn smaak.
Verpak in ʼn amber glasbottel wat 100 ml, 200 ml of 500 ml stroop bevat, toegerus met ʼn wit skroefprop en verpak in ʼn enkele kartondosie.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat

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Hierdie voubiljet is mees onlangs hersien op

22 Julie 2024

Registrasienommer

Moet nog toegeken word

adcock ingram

31960 08/2024