

SCHEDULING STATUS: S0

BIOPLUS SYRUP STRAWBERRY

Multiple ingredient formulation syrup

**Caffeine 90,0 mg, Calcium 41,8 mg, Vitamin B₃ 14,0 mg, Vitamin B₁ 4,2 mg,
Vitamin B₂ 3,7 mg, Vitamin B₅ 3,4 mg, Vitamin B₆ 2,5 mg, Vitamin B₁₂ 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, Sodium cyclamate 13,3 mg and
11,0 mg blend of Acesulfame and Sucralose 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 Strawberry is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take **Bioplus Syrup Strawberry** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **Bioplus Syrup Strawberry** 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 Strawberry** is and what it is used for
2. What you need to know before you take **Bioplus Syrup Strawberry**
3. How to take **Bioplus Syrup Strawberry**
4. Possible side effects
5. How to store **Bioplus Syrup Strawberry**
6. Contents of the pack and other information

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

Bioplus Syrup Strawberry 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 Strawberry

Do not take Bioplus Syrup Strawberry:

- 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 Strawberry**:

- If you experience hypersensitivity or allergic reaction, stop taking **Bioplus Syrup Strawberry** and consult a healthcare provider.
- **Bioplus Syrup Strawberry** 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); or
 - 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 Strawberry

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 Strawberry**) can intensify its effects on the heart. **Bioplus Syrup Strawberry** 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 Strawberry**) may decrease their effectiveness. Take antibiotic medicine at least 2 hours prior to, or 4 to 6 hours after taking **Bioplus Syrup Strawberry**.
- Consumption of caffeine (as in **Bioplus Syrup Strawberry**) 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 Strawberry**.

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

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

Total caffeine (as in **Bioplus Syrup Strawberry**) 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 Strawberry** 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 Strawberry** affects them.

Bioplus Syrup Strawberry contains:

- **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 Strawberry**.
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 Strawberry** will not have any noticeable effects.
- **Carmosine (E122)** which may cause allergic (hypersensitivity) reactions.
- **Propylene glycol** 19 mg in each dosage unit which is equivalent to 19 mg/10 ml.

3. How to take Bioplus Syrup Strawberry

Do not share medicines prescribed for you with any other person.

Always use **Bioplus Syrup Strawberry** 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 Strawberry than you should

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

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 Strawberry

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

4. Possible side effects

Bioplus Syrup Strawberry can have side effects. **Bioplus Syrup Strawberry** generally well tolerated.

Not all side effects reported for **Bioplus Syrup Strawberry** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **Bioplus Syrup Strawberry**, please consult your healthcare provider for advice.

If any of the following happens, stop using **Bioplus Syrup Strawberry** 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

allergic reaction to **Bioplus Syrup Strawberry**. 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 effects you can help provide more information on the safety of **Bioplus Syrup Strawberry**.

5. How to store Bioplus Syrup Strawberry

Store all medicines out of reach of children.

Store at or below 25 °C. 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 Strawberry 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

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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: Citric acid monohydrate, colour raspberry red H1277 (containing carmoisine (E122) and icing sugar), Dolsweet 16 Dolce (ADI 450 sweetener blend of acesulfame and sucralose), ethanol, hydrochloric acid (pH adjustment), flavour strawberry QL15904 (containing ascorbic acid, propylene glycol and sodium citrate), liquid glucose, mannitol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water, saccharin sodium, sodium chloride, sodium cyclamate and sucrose.

What Bioplus Syrup Strawberry looks like and contents of the pack

A clear, red liquid with a strawberry 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.

Holder of Certificate of Registration

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To be allocated.

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SKEDULERINGSSTATUS: S0

BIOPLUS SYRUP STRAWBERRY

Veelvoudige bestanddeel-formulering stroop

Kaffeïen 90,0 mg, Kalsium 41,8 mg, Vitamien B₃ 14,0 mg, Vitamien B₁ 4,2 mg,
Vitamien B₂ 3,7 mg, Vitamien B₅ 3,4 mg, Vitamien B₆ 2,5 mg, Vitamien B₁₂ 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, Natriumsiklmaat 13,3 mg en
11,0 mg vermenging van Asesulfaam en sukralose 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 Strawberry is beskikbaar sonder 'n doktersvoorskrif om u gesondheid te onderhou. U moet **Bioplus Syrup Strawberry** nietemin steeds omsigtig gebruik om die beste resultate daaruit te kry.

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

Wat in hierdie voubiljet is

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

1. Wat Bioplus Syrup Strawberry is en waarvoor dit gebruik word

Bioplus Syrup Strawberry is 'n 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 'n verbeterde gemoedstoestand tot gevolg het.

2. Wat u moet weet voordat u **Bioplus Syrup Strawberry** gebruik

Moenie Bioplus Syrup Strawberry 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 Strawberry**:

- Staak gebruik van **Bioplus Syrup Strawberry** en raadpleeg 'n gesondheidsorgverskaffer as u hipersensitiwiteit of 'n allergiese reaksie ervaar.
- **Bioplus Syrup Strawberry** BEVAT KAFFEÏEN.
 - Elke dosiseenheid (10 ml) stroop bevat 90 mg kaffeïen. 'n Koppie kitskoffie bevat ongeveer 80 mg kaffeïen.
 - Raadpleeg 'n 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 'n operasie (sjirurgie) moet ondergaan.
 - Gebruik van kaffeïen kan tot slaapgebrek lei.

Ander medisyne en Bioplus Syrup Strawberry

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 Strawberry**) kan die uitwerking daarvan op die hart verhoog. **Bioplus Syrup Strawberry** 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 Strawberry) kan hulle doeltreffendheid verminder. Neem antibiotiese medisyne ten minste 2 ure voor, of 4 tot 6 ure na gebruik van **Bioplus Syrup Strawberry**.

- Inname van kaffeïen (soos in **Bioplus Syrup Strawberry**) saam met ander medisyne (bv. bitterlemoenekstrak, sinefrien, oktopamien, efedra, efedrien) wat bloeddruk verhoog, of ander kaffeïen-bevattende produkte of voedsel (bv. medisyne, koffie, tee, kola, kakao, guarana-drinkies) 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 Strawberry** gebruik.

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

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

Totale kaffeïen-inname (soos in **Bioplus Syrup Strawberry**) 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 Strawberry** 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 Strawberry** dit beïnvloed nie.

Bioplus Syrup Strawberry bevat:

- **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 Strawberry** gebruik. Sukrose en glukose kan skadelik wees vir die tande.
- **Metiel parahidroksiebensoaat (E218)** en **propiel parahidroksiebensoaat (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 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 Strawberry** sal nie enige merkbare invloed hê nie.

- **Karmosien (E122)** wat allergiese reaksies (hipersensitiwiteit) kan veroorsaak.
- **Propileenglikol** 19 mg in elke dosiseenheid wat gelykstaande is aan 19 mg/10 ml.

3. Hoe om Bioplus Syrup Strawberry te gebruik

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

Gebruik **Bioplus Syrup Strawberry** 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 onverdund.
- Skud die bottel voor gebruik.
- 'n 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 Strawberry gebruik as wat u moes

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

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

As u vergeet om Bioplus Syrup Strawberry te gebruik

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

4. Moontlike neue-effekte

Bioplus Syrup Strawberry kan neue-effekte hê. **Bioplus Syrup Strawberry** word oor die algemeen goed verdra.

Nie alle neue-effekte wat vir **Bioplus Syrup Strawberry** aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies as u algemene gesondheid verswak of indien u enige nadelige gevolge tydens gebruik van **Bioplus Syrup Strawberry** ervaar.

PASIËNT INLIGTINGSBILJET

Staak gebruik van **Bioplus Syrup Strawberry** 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 'n ernstige allergiese reaksie vir **Bioplus Syrup Strawberry** gehad het. U mag dringende mediese sorg of hospitalisasie nodig hê.

Vertel u dokter as u enige van die volgende opmerk:

Minder algemene newe-effekte:

- 'n 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 Strawberry**.

5. Hoe om Bioplus Syrup Strawberry te bêre

Bêre alle medisyne buite bereik van kinders.

Bêre teen of benede 25 °C. Beskerm teen lig.

Hou die houer dig toe.

Moenie in 'n 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 Strawberry bevat:

Die aktiewe bestanddele is:

Elke 10 ml bevat:	
Kaffeïen	90,0 mg

PASIËNT INLIGTINGSBILJET

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: Sitroensuurmonohidraat, framboos rooi kleursel H1277 (bevat karmosien (E122) en versiersuiker), "Dolsweet 16 Dolce" (ADI 450 versoeter-mengsel van asesulfaam en sukralose), etanol, soutsuur (pH-aanpassing), aarbei geursel QL15904 (bevat askorbiensuur, propileenglikol en natriumsitraat), vloeibare glukose, mannitol, metielparahidroksiebensoaat (E218), propielparahidroksiebensoaat (E216), gesuiwerde water, natriumsakkarien, natriumchloried, natriumsiklamaat en sukrose.

Hoe Bioplus Syrup Strawberry lyk en inhoud van pak

'n Deurskynende, rooi vloeistof met 'n aarbeigeur.

Verpak in 'n amber glasbottel wat 100 ml, 200 ml of 500 ml stroop bevat, toegerus met 'n wit skroefprop en verpak in 'n enkele kartondosie.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat

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Hierdie voubiljet is mees onlangs hersien op

PASIËNT INLIGTINGSBILJET

18 Junie 2024

Registrasienuommer

Moet nog toegeken word.

31961 08/2024

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