

PROFESSIONAL INFORMATION
D 34.11 Vitamins. Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
BIOGEN VITAMIN B₁₂
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Vitamin B ₁₂ (as Methylcobalamin)	100 µg
--	--------

Contains sugar: 100 mg Isomalt and 203.40 mg Mannitol per tablet.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

 BIOGEN VITAMIN B₁₂ contributes to normal energy-yielding metabolism & the reduction of tiredness and fatigue.

 Vitamin B₁₂ is essential to red blood cell formation; normal function of the nervous system and immune system; and plays a factor in the maintenance of good health.

4.2 Posology and method of administration
Adults and children over 12 years of age:
Adults: Take one (1) tablet sublingually daily, may also be chewed, or as recommended by your healthcare provider.

Elderly: No specific dosage adjustment is required when treating healthy, older patients.

Children and adolescents: Not recommended for individuals below 3 years of age (see section 4.4).

4.3 Contraindications

- If you have a hypersensitivity to Methylcobalamin or any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

 Special care should be taken with BIOGEN VITAMIN B₁₂.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- It is advised to discuss Vitamin B₁₂ or folic acid deficiency with your healthcare provider as administration of >10 µg daily may produce a haematological response in patients.
- Patients who have early Leber's disease (hereditary optic nerve atrophy) have been found to suffer severe and swift optic atrophy when Vitamin B₁₂ is administered.
- Treatment of severe Vitamin B₁₂ megaloblastic anemia may result in severe hypokalemia.
- The additive effect of concomitantly administered products containing sugar as BIOGEN VITAMIN B₁₂ (Isomalt and Mannitol) and dietary intake thereof should be taken into account.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction

 No specific drug interaction studies have been performed on BIOGEN VITAMIN B₁₂.

Interactions with Medicines

- Vitamin B₁₂ is not a substitute for folic acid and since it might improve folic acid deficient megaloblastic anemia, unselective use of vitamin B₁₂ could mask the true diagnosis.
- Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect the blood tests to measure Vitamin B₁₂.
- Colchicine, aminoglycosides, certain anticonvulsants (e.g., phenytoin, Phenobarbital, primidone), para-aminosalicylic acid or excessive alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂. Vitamin C may destroy Vitamin B₁₂. Patients are advised to avoid ingesting large amounts of Vitamin C within 1 hour of oral Vitamin B₁₂ administration.

Interactions with Diseases / Impairments

- Hypokalemia and thrombocytosis could occur upon conversion of severe megaloblastic to normal erythropoiesis with Vitamin B₁₂ therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during oral administration.
- Vitamin B₁₂ deficiency may suppress the signs of polycythemia vera.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN VITAMIN B₁₂.
- Alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂.

Fertility, pregnancy and lactation

 The safety and efficacy of BIOGEN VITAMIN B₁₂ in pregnancy and lactation has not been established. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

4.6 Effects on ability to drive and use machines

 Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN VITAMIN B₁₂ does not affect their performance.

4.7 Undesirable effects

 Orally, Vitamin B₁₂ (Methylcobalamin) is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Frequent: Nausea, abdominal pain, indigestion and/ or digestive disorders, constipation and diarrhoea.

Nervous system disorders:

Frequency unknown: Headache and fatigue.

Skin and subcutaneous tissue disorders:

Frequent: Rash, itching, and anaphylaxis.

Frequency unknown: acneform, and bullous eruptions.

Description of selected adverse reactions

 BIOGEN VITAMIN B₁₂ may cause several adverse reactions, such as gastrointestinal disturbances, fever, chills, hot flushing, dizziness, malaise, acneform and bullous eruptions, and tremor.

Paediatric Population

 No clinical data are available on the effects of BIOGEN VITAMIN B₁₂.

Other special populations

 No clinical data are available on the effects of BIOGEN VITAMIN B₁₂ on other special populations.

Reporting of suspected adverse reactions

 Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.

4.8 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

 Vitamin B₁₂ is a group of cobalt-containing B complex vitamins, also known as cobalamins, synthesized by microorganisms.

5.1 Pharmacodynamic properties
Mechanism of action:

 Vitamin B₁₂ is essential to growth, cell reproduction, hematopoiesis, and nucleoprotein and myelin synthesis. Cells characterized by rapid division (e.g., epithelial cells, bone marrow, myeloid cells) appear to have the greatest requirement for vitamin B₁₂. Vitamin B₁₂ can be converted to coenzyme B₁₂ in tissues, and as such is essential for conversion of methylmalonate to succinate and synthesis of methionine from homocysteine, a reaction which also requires folate. In the absence of coenzyme B₁₂, tetrahydrofolate cannot be regenerated from its inactive storage form, 5-methyltetrahydrofolate, and a functional folate deficiency occurs. Vitamin B₁₂ also may be involved in maintaining sulfhydryl (SH) groups in the reduced form required by many SH-activated enzyme systems. Through these reactions, vitamin B₁₂ is associated with fat and carbohydrate metabolism and protein synthesis.

Pharmacodynamic effects:

 In humans; exogenous source of vitamin B₁₂ is required for nucleoprotein and myelin synthesis, cell production, normal growth, and for the maintenance of normal erythropoiesis.

5.2 Pharmacokinetic properties
Absorption:

 Vitamins B₁₂ is irregularly absorbed from the distal small intestine following oral administration. Vitamin B₁₂ absorption is an active process that requires gastric intrinsic factor. Intrinsic factor is a glycoprotein secreted by the gastric mucosa. Passive diffusion through the intestinal wall can occur but large amounts of B₁₂ are required (i.e. >1 mg). Following oral doses less than 3 mcg, peak plasma concentrations are not reached for 8 to 12 hours because the vitamin is transiently retained in the wall of the lower ileum.

 No clinical data are available on the effects of BIOGEN VITAMIN B₁₂.

Distribution:

 Vitamin B₁₂ is distributed into the liver, bone marrow, and other tissues, including the placenta. At birth, the blood concentration of vitamin B₁₂ imneonates is 3 to 5 times that of the mother. Total body stores of vitamin B₁₂ in healthy individuals are estimated to range from 1 to 11 mg, with an average of 5 mg; 50 to 90 % is stored in the liver. Vitamin B₁₂ is believed to be converted to coenzyme form in the liver and is probably stored in tissues in this form.

Metabolism:

 Vitamin B₁₂ is converted in tissues to active coenzymes, methylcobalamin and deoxyadenosylcobalamin; undergoes some enterohepatic recycling.

Excretion:

 About 3-8 mcg of B₁₂ is secreted into the GI tract daily via the bile; in normal subjects with sufficient intrinsic factor, all but about 1 mcg is reabsorbed. When B₁₂ is administered in doses which saturate the binding capacity of plasma proteins and the liver, the unbound B₁₂ is rapidly eliminated in the urine. Retention of B₁₂ in the body is dose-dependent.

Preclinical safety data

 When used orally and appropriately, Vitamin B₁₂ as in BIOGEN VITAMIN B₁₂ is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Carboxymethyl cellulose (CMC), Magnesium stearate, Citric acid anhydrous, Mannitol and Isomalt DC101.

6.2 Shelf Life

24 Months.

6.3 Special precautions for storage

Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents

60 White round tablets

The container is a 175 mL PET container. The cap is a white plastic cap with a tamper evident seal.

6.5 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

 Biogen,
 23 Stag Rd,
 Glen Austin,
 South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

November 2021.

JOB: BPS_Stress Relief_30s		SIZE: 210mm x 340mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Foil / Holographic Foil		<input type="checkbox"/> Matte <input type="checkbox"/> Gloss	
<input type="checkbox"/> Spot UV		<input type="checkbox"/> Doming <input type="checkbox"/> Embossing	
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: [S0]

PRODUCT NAME
BIOGEN VITAMIN B₁₂

Each tablet contains Vitamin B₁₂ (as Methylcobalain)
Contains sugar: 100 mg Isomalt and 203.40 mg Mannitol per tablet.

D 34.11 Vitamins. Complementary Medicine: Health Supplement
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.
BIOGEN VITAMIN B₁₂ is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN VITAMIN B₁₂ carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN VITAMIN B₁₂ with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN VITAMIN B₁₂ is and what it is used for.
2. What you need to know before you take BIOGEN VITAMIN B₁₂.
3. How to take BIOGEN VITAMIN B₁₂.
4. Possible side effects.
5. How to store BIOGEN VITAMIN B₁₂.
6. Contents of the pack and other information.

1. What BIOGEN VITAMIN B₁₂ is and what it is used for
BIOGEN VITAMIN B₁₂ contributes to normal energy-yielding metabolism & the reduction of tiredness and fatigue. Vitamin B₁₂ is essential to red blood cell formation; normal function of the nervous system and immune system; and plays a factor in the maintenance of good health.

2. What you need to know before you take BIOGEN VITAMIN B₁₂
Do not take BIOGEN VITAMIN B₁₂:

- If you have a hypersensitive (allergic) to any of the ingredients listed (see section 6).

Warnings and precautions
Special care should be taken with BIOGEN VITAMIN B₁₂.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- It is advised to discuss Vitamin B₁₂ or folic acid deficiency with your healthcare provider as administration of > 10 µg daily may produce a haematological response.
- If you have early Leber's disease (hereditary optic nerve atrophy) you may suffer from severe and swift optic atrophy when Vitamin B₁₂ is administered.
- Treatment of severe Vitamin B₁₂ megaloblastic anemia may result in severe hypokalemia.
- The additive effect of concomitantly administered products containing sugar as in BIOGEN VITAMIN B₁₂ (Isomalt and Mannitol) and dietary intake thereof should be taken into account.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

Children and adolescents
BIOGEN VITAMIN B₁₂ is not recommended for use in children under the age of 3 years.

Other medicines and BIOGEN VITAMIN B₁₂
Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine. It is advised to consult your doctor if you want to take BIOGEN VITAMIN B₁₂ combined with other medicines or treatments such as:

- Vitamin B₁₂ is not a substitute for folic acid and since it may improve folic acid deficient megaloblastic anemia, unselective use of vitamin B₁₂ could mask the true diagnosis.
- Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect the blood tests to measure Vitamin B₁₂.
- Colchicine, aminoglycosides, certain anticonvulsants (e.g., phenytoin, Phenobarbital, primidone), para-aminosalicylic acid or excessive alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂. Vitamin C may destroy Vitamin B₁₂. You are advised to avoid ingesting large amounts of Vitamin C within 1 hour of oral Vitamin B₁₂ administration.

Interactions with Diseases / Impairments

- Hypokalemia and thrombocytosis could occur upon conversion of severe megaloblastic to normal erythropoiesis with Vitamin B₁₂ therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during oral administration.
- Vitamin B₁₂ deficiency may suppress the signs of polycythemia vera.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN VITAMIN B₁₂.
- Alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂.

Pregnancy, breastfeeding and fertility
The safety and efficacy of BIOGEN VITAMIN B₁₂ in pregnancy and lactation has not been established.

Driving and using machines
Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN VITAMIN B₁₂ does not affect their performance.

3. How to take BIOGEN VITAMIN B₁₂
Do not share your medicines with any other person.

Always take BIOGEN VITAMIN B₁₂ exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: Take one (1) tablet sublingually daily, may also be chewed, or as recommended by your healthcare provider.
Elderly: No specific dosage adjustment is required when treating healthy, older patients.
Children and adolescents: Not recommended for individuals below 3 years of age.

If you take more BIOGEN VITAMIN B₁₂ than you should
No known information. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and the rest of the BIOGEN VITAMIN B₁₂ with you so the doctor will know what you have taken.

If you forget to take BIOGEN VITAMIN B₁₂
Do not take a double dose to make up for forgotten individual doses.

4. Possible of side effects
BIOGEN VITAMIN B₁₂ can have side effects.
Not all side effects reported for BIOGEN VITAMIN B₁₂ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN VITAMIN B₁₂, please consult your healthcare provider for advice.

Side effects associated:
Frequent: Nausea, abdominal pain, indigestion and/ or digestive disorders, constipation and diarrhoea. Rash, itching and anaphylaxis.
Frequency unknown: Headache and fatigue. Achniform, and bullous eruptions.

Should your general health worsen or if you experience any untoward effects while BIOGEN VITAMIN B₁₂, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.
By reporting side effects, you can help provide more information on the safety of BIOGEN VITAMIN B₁₂.

5. How to store BIOGEN VITAMIN B₁₂
Store at or below 25 °C.
Protect from light and moisture.
Store all medicines out of reach of children.
Do not use after the expiry date printed on the container.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What BIOGEN VITAMIN B₁₂ contains
Active ingredients per tablet Vitamin B₁₂ (as Methylcobalamin) 100 µg
Contains sugar: 100 mg Isomalt and 203.40 mg Mannitol per tablet.
The other ingredients are Carboxymethyl cellulose (CMC), Magnesium stearate, Citric acid anhydrous, Mannitol and Isomalt.

What BIOGEN VITAMIN B₁₂ looks like and contents of the pack
175 ml PET container with a Biogen lid.
BIOGEN VITAMIN B₁₂ is a white, round tablet.

Holder of certificate of registration
Biogen,
23 Stag Rd,
Glen Austin,
South Africa

This leaflet was last revised in
November 2021.

Registration number
Will be allocated by SAHPRA upon registration

PASİENTINLIGTINGSBLAD

SKEDULERINGSTATUS: [S0]

PRODUKNAAM
BIOGEN VITAMIN B₁₂

Elke tablet bevat: Vitamien B12 (as Metielkobalamien)
Bevat suiker: 100 mg Isomalt en 203.4 mg Mannitol per tablet.

D 34.12 Meervoudige Bestandeel Formulasie. Komplementêre Medisyne. Gesondheidsaanvulling.
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN VITAMIN B₁₂ is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN VITAMIN B₁₂ nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN VITAMIN B₁₂ met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteker indien u verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is BIOGEN VITAMIN B₁₂ en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN VITAMIN B₁₂ neem.
3. Hoe om BIOGEN VITAMIN B₁₂ te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN VITAMIN B₁₂ te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIOGEN VITAMIN B₁₂ en waarvoor word dit gebruik
BIOGEN VITAMIN B₁₂ dra by tot normale energie-lewende metabolisme en die vermindering van moegheid en moegheid. Vitamien B₁₂ is noodsaaklik vir rooibloedselvorming; normale funksie van die senuweestelsel en immuunstelsel; en speel 'n faktor in die handhawing van goeie gesondheid.

2. Wat u moet weet voordat u BIOGEN VITAMIN B₁₂ neem
Moenie BIOGEN VITAMIN B₁₂ neem nie:

- Indien u hipersensitief (allergies) is vir enige van die ander bestanddele gelys (sien afdeling 6).

Waarskuwings en voorsorgmaatreëls
Spesiale sorg moet toegepas word met die gebruik van BIOGEN VITAMIN B₁₂. Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik. Let asseblief op die volgende:

- Dit word aangeraai om 'n vitamien B₁₂ of foliensuurtekort met u gesondheidsorgverskaffer te bespreek aangesien toediening van > 10 µg daaglik 'n hematologiese reaksie kan veroorsaak.
- As u gediagnoseer is met vroeë Leber se siekte (oorerflikte optiese senuwee-atrofie) kan u tot ernstige en vinnige optiese atrofie ly wanneer Vitamien B₁₂ toegedien word.
- Behandeling van ernstige vitamien B₁₂ megaloblastiese anemie kan ernstige hipokalemie tot gevolg hê.
- Die bykomende effek van gelyktydig toegedienende produkte wat suiker bevat, so ook in BIOGEN VITAMIN B₁₂ (Isomalt en Mannitol) en die dieetinnam daarvan moet in ag geneem word.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente
BIOGEN VITAMIN B₁₂ word nie vir kinders onder die ouderdom van 3 jaar aanbeveel nie

Ander medisyne en BIOGEN VITAMIN B₁₂
Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereeelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN VITAMIN B₁₂ wil kombineer saam met ander medisyne of behandelinge soos:

- Vitamien B₁₂ is nie 'n plaasvervanger vir foliensuur nie en aangesien dit megaloblastiese anemie met foliensuurtekorte kan verbeter, kan onselektiewe gebruik van vitamien B₁₂ die ware diagnose masker.
- Antibiotika (vir gebruik in behandeling van infeksies) en Antimetaboliete (gebruik om sommige kankers te behandel) kan bloedtoetsresultate om Vitamien B₁₂ vlakke vas te stel beïnvloed.
- Kolgisien, Aminoglikosiede, sekere Antikonvulsiewe middels (bv. Fenitoin, Fenobarbital, Primidoon), Para-aminosalisiesuur of oormatige alkoholinnam vir langer as 2 weke kan die absorpsie van Vitamien B₁₂ benadeel. Vitamien C kan Vitamien B₁₂ vernietig. U word aangeraai om groot hoeveelhede Vitamien C te vermyn binne 1 uur na orale Vitamien B₁₂ toediening.

Interaksies met siektes / gestremdhede

- Hipokalemie en trombose kan voorkom met die omskakeling van ernstige megaloblastiese na normale eritropoiese met Vitamien B₁₂-terapie. Daarom moet serumkaliumvlakke en die bloedplaatjietelling noukeurig gemonitor word tydens orale toediening.
- Vitamien B₁₂-tekort kan die tekens van polycythemia vera onderdruk.

Interaksies met voedsel

- Vitamien, minerale en voedingsowwe wat van ander bronne verkry word, moet in ag geneem word wanneer BIOGEN VITAMIN B₁₂ voorgeskryf / voorgestel word.
- Alkoholinnam vir periodes langer as 2 weke kan die absorpsie van Vitamien B₁₂ beïnvloed.

Swangerskap, borsvoeding en vrugbaarheid
Die veiligheid en doeltreffendheid van BIOGEN VITAMIN B₁₂ tydens swangerskap en laktasie is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik totdat hulle redelik seker is dat BIOGEN VITAMIN B₁₂ nie hul werkverrigting beïnvloed nie.

3. Hoe om BIOGEN VITAMIN B₁₂ te neem
Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN VITAMIN B₁₂ altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteker vir u aanbeveel het. Vra gerus u dokter of apteker indien u onseker is.

Volwassenes: Neem een (1) tablet sublingual daaglik, kan ook gekou word, of soos aanbeveel deur jou gesondheidsorgverskaffer.
Bejaardes: Geen spesifieke dosisaanpassing word benodig wanneer gesonde, ouer pasiënte behandel word nie.
Kinders en adolessente: Word nie aanbeveel by kinders onder die ouderdom van 3 jaar nie.

Wat om te doen indien u meer BIOGEN VITAMIN B₁₂ geneem het as wat u moet
Geen bekende informasie. Indien u meer BIOGEN VITAMIN B₁₂ geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Neem hierdie inligtingsblad en die oorblywende BIOGEN VITAMIN B₁₂ saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN VITAMIN B₁₂ te neem
Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike nuwe-effekte
BIOGEN VITAMIN B₁₂ kan nuwe-effekte hê.
Nie alle nuwe-effekte wat aangemeld is vir BIOGEN VITAMIN B₁₂ is in hierdie voulibjel ingestuit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN VITAMIN B₁₂, raadpleeg u gesondheidsorgwerker vir advies.

Neuwe-effekte geassosieer:
Algemeen: Naarheid, buikpyn, spysvertering en/of spysverteringsstoornisse, hardlywigheid en diarree. Uitslag, jeuk en anafisie.
Frekwensie onbekend: Hoofpyn en moegheid. Achniform, en bulagtige uitbarstings.

Raadpleeg u dokter, apteker of ander gene -esheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN VITAMIN B₁₂ neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteker daarvan in kennis gestel word.

Rapportering van nuwe-effekte
Indien u nuwe-effekte ondervind, bespreek dit met u dokter of apteker. U kan ook nuwe-effekte aan SAHPRA rapporteer via die Adverse Drug Reactions Reporting Form, wat aanyln by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN VITAMIN B₁₂ te verskaf.

5. Hoe om BIOGEN VITAMIN B₁₂ te bêre
Bêre by of onder 25 °C.
Beskerm teen lig en vog.
Bêre alle medisyne buite bereik van kinders.
Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat BIOGEN VITAMIN B₁₂ bevat
Aktiewe bestanddele per tablet, Vitamien B12 (as Metielkobalamien)
Bevat Bevat suiker: 100 mg Isomalt en 203.4 mg Mannitol per tablet.
Die ander bestanddele is Karboksietielcellulose (CMC), Magnesiumstearaat, Sitroensuur watervry, Mannitol en Isomalt.

Hoe BIOGEN VITAMIN B₁₂ lyk en inhoud van die verpakking
175 ml PET container with a Biogen lid.
BIOGEN VITAMIN B₁₂ is 'n wit, ronde tablet.

Houer van die registrasiesertifikaat
Biogen,
23 Stag Rd,
Glen Austin,
South Africa

Hierdie inligtingsblad is laas hersien in
November 2021.

Registrasienuommer
Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_Stress Relief_30s		SIZE: 210mm x 340mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input checked="" type="checkbox"/> K	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot
<input type="checkbox"/> Foil / Holographic Foil		<input type="checkbox"/> Matte	<input type="checkbox"/> Gloss
<input type="checkbox"/> Spot UV		<input type="checkbox"/> Doming	<input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			