

PROFESSIONAL INFORMATION
D 34.6 Fats, Oils and Fatty Acids. 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 CBD SLEEP
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml (30 drops) of BIOGEN CBD SLEEP contains 20 mg *Cannabis sativa* L. cannabidiol (CBD isolate).

Sugar Free. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oil (30 ml)

Light yellow oil with a natural, botanical taste.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN CBD SLEEP, a source of antioxidants for the maintenance of good health, may assist with the relief of restlessness and sleeplessness.

4.2 Posology and method of administration

Adults: Take up to 30 drops / 1 ml (20 mg CBD) daily as a single or divided dose. Place the drops under the tongue and hold for 30 - 90 seconds before swallowing. SHAKE WELL BEFORE USE. **Do not exceed the recommended maximum daily dose of 20 mg CBD.**

The safety and efficacy of BIOGEN CBD SLEEP in children has not yet been established. Not allowed in children under 18 years.

When discontinuing BIOGEN CBD SLEEP, the dose should be decreased gradually.

4.3 Contraindications:

- If you have a hypersensitivity to cannabidiol or any of the excipients listed in 6.1.
- Not recommended during pregnancy and lactation.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN CBD SLEEP.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- The use of BIOGEN CBD SLEEP in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes, therefore dosage adjustments are required and should be discussed with your relevant healthcare provider.
- BIOGEN CBD SLEEP can cause somnolence and sedation.
- Patients who have had or have mood problems or depression should be monitored.
- BIOGEN CBD SLEEP not recommended for use in children under the age of 18 years.

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 interactions
Interactions with Medicines

- The concomitant use of pain medication such as methadone, may cause additive adverse effects.
- Simultaneous use of BIOGEN CBD SLEEP and antiepileptic/anticonvulsant medication (such as brivaracetam, eslicarbazepine, rufinamide, zonisamide, valproate, topiramate and stiripentol) could increase antiepileptic/anticonvulsant plasma levels and elevate liver enzyme concentrations. In addition, valproate may also result in low blood platelet count.
- Although speculated, simultaneous use of BIOGEN CBD SLEEP and birth control medication may cause interactions. If a female patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.
- BIOGEN CBD SLEEP may interact with central nervous system (CNS) depressants (for example barbiturates and benzodiazepines) and alcohol may increase the risk of sedation and somnolence. Herbs/supplements with sedative properties, such as calamus, California poppy, catnip, hops, Jamaican dogwood, kava, L-tryptophan, melatonin, sage, St. John's wort, sassafras, skullcap, and other may theoretically also have additive sedative properties when used simultaneously with CBD.
- Co-administration of immunosuppressants (such as tacrolimus and sirolimus) and CBD may result in elevated immunosuppressant plasma levels and consequently additive adverse effects.
- Simultaneous use of CBD and everolimus (kinase inhibitor) may increase everolimus levels which might cause additive adverse effects.
- Moderate or strong inhibitors of CYP3A4 or CYP2C19 may increase CBD plasma concentrations. This includes antiretroviral medication like protease inhibitors, antibiotics like erythromycin and clarithromycin, antidepressants like fluoxetine and fluvoxamine and proton pump inhibitors like omeprazole.
- Alternatively, the co-administration with strong inducers of CYP3A4 or CYP2C19 may decrease CBD plasma concentrations, which may lower the efficacy of CBD-containing products. This includes phenobarbital, phenytoin, carbamazepine, primidone and rifampicin.
- Simultaneous use may interfere with blood thinning medicines, like ticlopidine, warfarin, aspirin etc.

Interactions with Diseases / Impairments

- The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes (see section 4.4).
- CBD may worsen symptoms associated with Parkinson disease.

Interactions with Foods

- As CBD is highly lipophilic, it dissolves easily in the fat content of food. Thus, simultaneous consumption of CBD and high fatty food may increase the solubility, absorption and bioavailability of CBD.
- Do not take with alcohol as it may increase the risk of sedation and somnolence.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established. Not recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

As CBD may cause delayed reactions, drowsiness and sedation, it is advised that patients taking BIOGEN CBD SLEEP should not drive or operate machinery until they are reasonably certain that it does not adversely affect their ability to drive or operate machinery.

4.8 Undesirable effects

Orally, BIOGEN CBD SLEEP is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Frequent: Dry mouth, diarrhoea, vomiting, decreased appetite, weight loss and abdominal pain or discomfort.

Nervous system disorders:

Frequent: Somnolence, sedation, psychomotor slowing, lethargy, dizziness and fatigue.

Investigations:

Frequency unknown: Elevated liver transaminases.

Description of selected adverse reactions

CBD may cause several adverse reactions, of which weight loss, diarrhoea, decreased appetite, somnolence, sedation, lethargy, fatigue and elevated liver transaminases are CBD dose-dependent.

Dizziness is mostly reported when CBD is concomitantly used with clobazam, a benzodiazepine. Elevated liver transaminases mostly appears in patients with baseline elevated liver enzymes or in patients who concomitantly consume valproate or clobazam. Discontinuation or dose adjustment of valproate or clobazam is recommended if elevated liver transaminases are detected.

Paediatric Population

BIOGEN CBD SLEEP is not recommended for use in children under the age of 18 years.

Other special populations

No clinical data are available on the effects of BIOGEN CBD SLEEP 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: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

No known side effects were reported for overdosage of CBD.

CBD overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

BIOGEN CBD SLEEP, a source of antioxidants for the maintenance of good health, may assist with the relief of restlessness and sleeplessness.

Pharmacodynamic properties

Mechanism of action:

CBD can interact or alter the endocannabinoid signalling pathways (via the cannabinoid receptors) and the non-endocannabinoid pathways (interactions with serotonin 5-HT1A receptors, GPR55 receptors and vanilloid-1 receptors). CBD also inhibits the degradation of the endocannabinoid, anandamide, which may contribute to its antipsychotic effects.

Pharmacodynamic effects:

Cannabis sativa L. cannabidiol (CBD): Results from pre-clinical studies suggest CBD has anti-inflammatory, analgesic, antiemetic, antipsychotic, anti-ischemic, anxiolytic, and antiepileptiform effects.

Pharmacokinetic properties

Absorption: Oral bioavailability of CBD is very low (13 % - 19 %). This can be ascribed to first pass metabolism.

Distribution: CBD is rapidly distributed into the tissues (volume of distribution: approximately 32 L/kg). Due to the high lipophilicity of CBD, it may preferentially accumulate in the adipose tissue. CBD and its metabolites are more than 94 % protein bound.

Metabolism: CBD is vastly metabolized in the liver. It undergoes hydroxylation, oxidation, beta-oxidation, conjugation, and epoxidation.

Excretion: The half-life of CBD is between 56 to 61 hours. CBD is excreted in the faeces, with minor renal clearance.

Preclinical safety data

When used orally and appropriately in adults, CBD is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

Alpha tocopheryl acetate (vitamin E), and Medium chain triglyceride oil.

6.2 Incompatibilities

No compatibility studies has been performed, BIOGEN CBD SLEEP must not be mixed with other medications.

6.3 Shelf Life

23 Months.

6.4 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.

6.5 Nature and contents

The container is a 30 mL amber glass bottle with a graduated pipette. The cap is a black plastic cap with a tamper evident seal.

6.6 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

August 2021.

JOB: BPS_CBD Sleep Oil 30ml	SIZE: 246mm 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"/>	
COLOUR:  K	FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornig <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

BIOGEN CBD SLEEP

Cannabidiol
Sugar free.

D 34.6 Fats, Oils and Fatty Acids.

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

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

1. What BIOGEN CBD SLEEP is and what it is used for

BIOGEN CBD SLEEP, a source of antioxidants for the maintenance of good health and may assist with the relief of restlessness and sleeplessness.

2. What you need to know before you take BIOGEN CBD SLEEP

Do not take BIOGEN CBD SLEEP:

- If you are hypersensitive (allergic) to cannabidiol or any of the ingredients of BIOGEN CBD SLEEP (see section 6).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

- Use with caution if you have mild or severe hepatic impairment (liver disease).
- CBD may cause delayed reactions, sedation and drowsiness.
- Patients who have had or have mood problems or depression should be monitored.
- Use with caution in patients with Parkinson disease.
- Not recommended for use in children under the age of 18 years.

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

Children and adolescents

BIOGEN CBD SLEEP is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN CBD SLEEP

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 CBD SLEEP combined with other medicines or treatments such as:

- Pain medication (methadone), as it may cause additive adverse effects.
- Antiepileptic or anticonvulsant medication (such as brivaracetam, eslicarbazepine, rufinamide, zonisamide, valproate, topiramate and stiripentol) could result in liver damage due to elevated liver enzymes. In addition, valproate may also result in low blood platelet count.
- Central nervous system (CNS) depressants, as it may increase the risk of sedation and somnolence. Herbs/supplements with sedative properties, such as calamus, California poppy, catnip, hops, Jamaican dogwood, kava, L-tryptophan, melatonin, sage, St. John's wort, sassafras, skullcap, and other may theoretically also have additive sedative properties when used concomitantly with CBD.
- Immunosuppressants (such as tacrolimus and sirolimus), as it may result in elevated immunosuppressant plasma levels and consequently additive side effects.
- Kinase inhibitor, everolimus, as co-administration may cause additive adverse effects.
- Antiretroviral medication, antibiotics like erythromycin and clarithromycin, antidepressants like fluvoxamine and proton pump inhibitors (PPI's) like omeprazole, since these might increase CBD plasma concentrations leading to a greater risk of side effects.
- Phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin, as it will decrease CBD plasma concentrations, which may lower the efficacy of CBD-containing products.
- Birth control medication may cause interactions. If a patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.

BIOGEN CBD SLEEP with food and drink

Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.

A meal high in fat may improve CBD absorption and bioavailability.

Consuming alcohol in combination with CBD may increase the risk of sedation and drowsiness.

Pregnancy, breastfeeding and fertility

Not recommended for use during pregnancy or lactation.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. It is possible that BIOGEN CBD SLEEP would affect the ability to drive or operate machinery, as CBD may cause delayed reactions, drowsiness and sedation. Please exercise caution until you are certain that your ability to perform such activities is not affected.

3. How to take BIOGEN CBD SLEEP

Do not share your medicines with any other person.

Always take BIOGEN CBD SLEEP 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 up to 30 drops (20 mg CBD) daily as a single or divided dose. Place the drops under the tongue and hold for 30 - 90 seconds before swallowing. SHAKE WELL BEFORE USE. **Do not exceed the recommended maximum daily dose of 20 mg CBD.**

If you take more BIOGEN CBD SLEEP 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 CBD SLEEP oil with you so the doctor will know what you have taken.

If you forget to take BIOGEN CBD SLEEP

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

4. Possible side effects

BIOGEN CBD SLEEP can have side effects.

Not all side effects reported for BIOGEN CBD SLEEP are included in this leaflet. Should your general health worsen or if you experience any untowards effects while taking BIOGEN CBD SLEEP, please consult your healthcare provider for advice.

Side effects associated with CBD:

Frequent: Diarrhea, dry mouth, vomiting, decreased appetite, weight loss and abdominal pain or discomfort.

Frequent: Drowsiness, sedation, delayed reactions, lethargy, dizziness and fatigue.

Frequency unknown: Elevated liver enzymes.

Should your general health worsen or if you experience any untoward effects while BIOGEN CBD SLEEP, 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 CBD SLEEP.

5. How to store BIOGEN CBD SLEEP

- 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.
- Discard any unused cannabidiol remaining after 12 weeks of first opening the bottle.
- 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 CBD SLEEP contains

Active ingredient per 1 ml (30 drops) is 20,00 mg *Cannabis sativa* L. Cannabidiol (CBD isolate).

The other ingredients are Alpha tocopheryl acetate (vitamin E), and Medium chain triglyceride oil.

What BIOGEN CBD SLEEP looks like and contents of the pack

A 30 ml amber glass bottle with a graduated pipette. The cap is a black plastic cap with a tamper evident seal. Packed in a unit carton.

BIOGEN CBD SLEEP oil is a light yellow coloured oil with a natural, botanical taste.

Holder of certificate of registration

Biogen,
23 Stag Rd,
Glen Austin,
South Africa

This leaflet was last revised in

August 2021.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS: S0

BIOGEN CBD SLEEP

Kannabidiol
Suikervry.

D 34.6 Vette, Olies en Vetsure.

Komplementêre Medisyne. Gesondheidsaanvulling.

Hierdie ongeregistreerde medisyne is nie deur die 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 CBD SLEEP is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN CBD SLEEP nietiemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN CBD SLEEP 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 CBD SLEEP en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN CBD SLEEP neem.
3. Hoe om BIOGEN CBD SLEEP te neem.
4. Moontlike newe-effekte.
5. Hoe om BIOGEN CBD SLEEP te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIOGEN CBD SLEEP en waarvoor word dit gebruik

BIOGEN CBD SLEEP, 'n bron van antioksidante vir die instandhouding van gesondheid, en kan help met die verligting van rusteloosheid en slapeloosheid.

2. Wat u moet weet voordat u BIOGEN CBD SLEEP neem

Moenie BIOGEN CBD SLEEP neem nie:

- Indien u allergies is vir cannabidiol, of enige van die bestanddele van BIOGEN CBD SLEEP (sien afdeling 6).
- Indien u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls

- Gebruik versigtig indien u matige tot ernstige lewerprobleme.
- CBD kan vertraagde reaksies, sedasie en lomerigheid veroorsaak.
- Monitor pasiënte wat gemoedsprobleme of depressie het, of gehad het.
- Gebruik versigtig in pasiënte met Parkinson-siekte.
- Moet nie vir kinders onder die ouderdom van 18 jaar toegedien word nie.

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 CBD SLEEP word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

Andere medisyne en BIOGEN CBD SLEEP

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN CBD SLEEP wil kombineer saam met ander medisyne of behandeling soos:

- Pynmedikasie (metadool), omrede die gesamentlike gebruik addisionele nadelige gevolge kan hê.
- Antiepileptiese of antikonvulsie medikasie (soos brivaracetam, eslicarbazepien, rufinamide, zonisamide, valproaat, topiramaat en stiripentol) omrede dit kan lei tot lewerskade weens verhoogde transaminase ensiemvlakke in die lewer. Boonop mag valproaat ook lei tot 'n verlaagde bloedplaatjie telling.
- Sentrale senuweestelsel (SSS) depressante (bv. zopikloon, diasepien, aprasolam, klobazam ens.), omdat die gesamentlike gebruik met CBD die risiko van sedasie en lomerigheid kan verhoog. Kruid/aanvullings met sederende eienskappe soos Kaliforniese papawer, katkruid, hop, Jamaican dogwood, kava, L-tryptofaan, melatonien, salie, Johanneskruid, sassafras, skullcap en ander, kan teoreties ook die risiko vir sedasie verhoog wanneer dit saam met CBD gebruik word.
- Immuunonderdrukkers (soos takrolimus en sirolimus), omrede die gesamentlike gebruik die vlakke van hierdie onderdrukkers in die plasma kan verhoog en gevolglik die newe-effekte vererger.
- Kinase inhibeerder, everolimus, omrede die gesamentlike gebruik die newe-effekte van everolimus kan vererger.
- Anti-retrovirale middels, antibiotika soos eritromisien en klaritromisien, antidepressante soos fluvoxamine, en proton pomp inhibeerdere (PPI's) soos omeprasool, aangesien hierdie middels die plasma vlakke van CBD kan verhoog en sodoende die newe-effekte daarvan vererger.
- Fenobarbital, fenitoien, karbamasepien, prednisoen en rifampisien, omrede dit CBD plasma vlakke verlaag en gevolglik ook die effektiwiteit van CBD verminder.

BIOGEN CBD SLEEP met kos en drinkgoed

Gebruik hierdie produk saam met voedsel as deel van 'n gesonde, gebalanseerde dieet, nie as 'n plaasvervanger daarvoor nie.

'n Maaltyd hoog in vet kan die opname en bio beskikbaarheid van CBD verbeter.

Die gebruik van alkohol in kombinasie met CBD kan die risiko van sedasie en lomerigheid verhoog.

Swangerskap, borsvoeding en vrugbaarheid

Nie aanbeveel vir gebruik tydens swangerskap en laktasie nie.

Indien u swanger is of u baba borsvoed, dink dat u swanger is, of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of gesondheidsorgwerker voordat u hierdie medisyne gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die uitwerking op die vermoë om te bestuur of masjinerie te gebruik nie. Dit is moontlik dat BIOGEN CBD SLEEP die vermoë om te bestuur of gebruik van masjinerie kan beïnvloed, aangesien CBD vertraagde reaksies, lomerigheid en sedasie kan veroorsaak. Wees asseblief versigtig totdat u seker is dat u vermoë om sulke aktiwiteite uit te voer nie beïnvloed word nie.

3. Hoe om BIOGEN CBD SLEEP te neem

Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN CBD SLEEP 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 tot en met 30 druppels (20 mg CBD) daaglik in 'n enkele of verdeelde dosis. Plaas die druppels onder die tong en hou dit 30 - 90 sekondes voordat dit ingesluk word. SKUD DIE BOTTEL GOED VOOR GEBRUIK. **Moenie die aanbevole maksimum daaglikse dosis van 20 mg CBD oorskry nie.**

Wat om te doen indien u meer BIOGEN CBD SLEEP geneem het as wat u moet

Geen bekende informasie. Indien u meer BIOGEN CBD SLEEP geneem het as wat u moet, 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 CBD SLEEP olie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN CBD SLEEP te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike newe-effekte

BIOGEN CBD SLEEP kan newe-effekte hê.

Nie alle newe-effekte wat aangemeld is vir BIOGEN CBD SLEEP is in hierdie voorbeeld ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN CBD SLEEP, raadpleeg u gesondheidsorgwerker vir advies.

Newe-effekte geassosieer met CBD:

Algemeer: Diarree, droë mond, braking, verminderde eetlus, gewigsverlies en buikpyn of ongemak.

Algemeer: Lomerigheid, verdowing, vertraagde reaksies, lusteloosheid, duiseligheid en moegheid.

Frekwensie onbekend: Verhoogde lewerensiem.

Raadpleeg u dokter, apteker of ander geneesheer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN CBD SLEEP neem.

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

Rapportering van newe-effekte

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

Deur newe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN CBD SLEEP te verskaf.

5. Hoe om BIOGEN CBD SLEEP te bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Gooi ongebruikte kannabidiol weg na 12 weke vandat die bottel ooggemaak is.
- 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 CBD SLEEP bevat

Aktiewe bestanddeel per 1 ml (30 druppels) is 20,00 mg *Cannabis sativa* L. Kannabidiol (CBD isolaat).

Die ander bestanddele is Alfa-tokoferielasetaat (vitamien E) en Medium ketting trigliseried olie.

Hoe BIOGEN CBD SLEEP lyk en inhoud van die verpakking

'n 30 ml amber glasbottel met 'n gegradeerde pipet. Die doppie is 'n swart plastiek dop met 'n peutervrye seël. Verpak in 'n eenheidskarton.

BIOGEN CBD SLEEP olie is 'n liggeel olie met 'n natuurlike, botaniese smaak.

Houer van die registrasiesertifikaat


Biogen,
23 Stag Rd,
Glen Austin,
South Africa

Hierdie inligtingsblad is laas hersien in

Augustus 2021.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_CBD Sleep Oil 30ml		SIZE: 246mm 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"/>			
COLOUR:  K		FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornig <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.			