

**PROFESSIONAL INFORMATION**
**D 33.6 Western Herbal Medicine. Complementary Medicine: Discipline-Specific Traditional Claims.**

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 RECOVER & REPAIR**
**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains

<i>Harpagophytum procumbens</i> (Burch.) DC. ex Meisn. (Devil's claw) [Root; 4:1 Extract, providing 1,8 g dried herb equivalent]	450,00 mg
<i>Cannabis sativa</i> L. cannabidiol (CBD isolate)	20,00 mg
<i>Curcuma longa</i> L. (Turmeric) [Root; 20:1 Extract standardised to 95 % curcumins, providing 0,2 g dried herb equivalent]	10,00 mg

Vegetable Capsule  
Sugar Free

For the full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Capsules

**4. CLINICAL PARTICULARS**
**4.1 Therapeutic indications**

BIOGEN CBD RECOVER & REPAIR, may assist to relieve joint pain associated with osteoarthritis and inflammation.

**4.2 Posology and method of administration**

*Adults:* Take 1 Capsule Daily. Each capsule contains 20 mg CBD. **Do not exceed the recommended maximum daily dose of 20 mg CBD.**

The safety and efficacy of BIOGEN CBD RECOVER & REPAIR in children has not yet been established, not allowed in children under 18 years.

When discontinuing BIOGEN CBD RECOVER & REPAIR, the dose should be decreased gradually.

**4.3 Contraindications:**

- If you have a hypersensitivity to Cannabidiol, Devil's Claw, Turmeric, 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 RECOVER & REPAIR.

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 RECOVER & REPAIR 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.
- Patients with gallstones, gastric-, duodenal- and stomach ulcers, bile duct obstruction, or excess stomach acid are advised to discuss dosage requirements with their relevant healthcare provider
- BIOGEN CBD RECOVER & REPAIR can cause somnolence and sedation.
- Patients who have had or had mood problems or depression should be monitored.
- BIOGEN CBD RECOVER & REPAIR not recommended for use in children.

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**

Interactions can occur. Give your healthcare provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

**Interactions with Medicines**

BIOGEN CBD RECOVER & REPAIR may interact with the following medicines, herbs or supplements:

- The concomitant use of pain medication such as methadone, may cause additive adverse effects.
- Simultaneous use of BIOGEN CBD RECOVER & REPAIR 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 RECOVER & REPAIR 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 RECOVER & REPAIR 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, saffras, 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 and 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.
- The possibility of excessive doses interfering with existing treatment for cardiac disorders or with hypo/hypertensive therapy should be considered.

**Interactions with Foods**

- As CBD is highly lipophilic, it dissolves easily in the fat content of food. Thus, the 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**

It is advised that patients taking BIOGEN CBD RECOVER & REPAIR 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 RECOVER & REPAIR is well-tolerated but it can have side effects.

**Adverse reactions associated with BIOGEN CBD RECOVER & REPAIR:**

Gastrointestinal disorders: (*Frequent*): Dry mouth, diarrhea, 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.

Devil's Claw may cause allergic reactions, headaches, stomach upset, and acouphenes.

**Paediatric Population**

Not recommended for the use in children under the age of 18 years.

**Other special populations**

No clinical data are available on the effects of BIOGEN CBD RECOVER & REPAIR on other special populations.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of BIOGEN CBD RECOVER & REPAIR is important. It allows continued monitoring of the benefit/risk balance of BIOGEN CBD RECOVER & REPAIR. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **Adverse Drug Reaction 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 BIOGEN CBD RECOVER & REPAIR. Overdose is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

BIOGEN CBD RECOVER & REPAIR may assist to relieve joint pain associated with osteoarthritis and inflammation.

**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.

Devil's Claw, the harpagoside can induce beneficial effects, inhibition by harpagoside of the 5-lipoxygenase enzyme responsible for the activation of the chain mechanism leading to the production of endogenous substances that ease inflammatory processes.

Curcumin (Turmeric), may have anti-inflammatory activity, possibly by inhibiting cyclooxygenase-2 (COX-2), prostaglandins, leukotrienes, and other cytokines involved in pro-inflammatory signaling pathways.

**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.

*Harpagophytum procumbens* extract (Devil's Claw): Clinical trials showed that a dose-dependent relationship between the serum levels of harpagoside and the degree of inhibition of leucotrienes' synthesis (anti-inflammatory effect). It may therefore assist with the maintenance or improvement of articular mobility or joint flexibility.

Curcumin may inhibit inflammatory enzymes such as collagenase, elastase, and hyaluronidase, and reduces the inflammatory markers interleukin-6 and high-sensitivity C-reactive protein (hs-CRP).

**Pharmacokinetic properties**
**Absorption:**

Oral bioavailability of CBD is very low (13 % - 19 %). This can be ascribed to first pass metabolism. Plasma harpagoside concentrations after oral administration of devil's claw extract may be low. Oral bioavailability of curcumin is very low, due to metabolism in the liver and intestines.

Absorption appears to increase when taken with food.

**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. Devil's Claw is distributed in the blood stream.

**Metabolism:**

CBD is vastly metabolized in the liver. It undergoes hydroxylation, oxidation, beta-oxidation, conjugation, and epoxidation. Devil's Claw is metabolized by the intestinal bacteria. Transformation of the iridoids harpagide, harpagoside and 8-O-(p-coumaroyl)-harpagide into the pyridine monoterpene alkaloid aucubinine B.

**Excretion:**

The half-life of CBD is between 56 to 61 hours. CBD is excreted in the faeces, with minor renal clearance. The half-life of Devil's Claw is between 5 to 6 hours and excreted in the fecal flora. Curcumin is present in the plasma as glucuronide and sulphate conjugates, the half-lives of these conjugates are 6-24 hours and excreted in the feces and urine.

**Preclinical safety data**

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

**6. PHARMACEUTICAL PARTICULARS**
**6.1 List of excipients**

White vegetable capsules, Magnesium stearate, Microcrystalline cellulose.

**6.2 Incompatibilities**

BIOGEN CBD RECOVER & REPAIR must not be mixed with other medicines.

**6.3 Shelf Life**

24 Months.

**6.4 Special precautions for storage**

Store in a cool dry place, at or below 25 °C.  
KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

175 ml PET Container with a Biogen lid. Packed in a carton.  
BIOGEN CBD RECOVER & REPAIR is size 00 white vegetable capsules.

**6.6 Special precautions for disposal and other handling**

Return all unused BIOGEN CBD RECOVER & REPAIR capsules to your pharmacist.  
Do not dispose of unused BIOGEN CBD RECOVER & REPAIR capsules in drains or sewerage systems (e.g. toilets).

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Biogen,  
23 Stagg 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**

July 2021.

<b>JOB:</b> BPS_CBD RECOVER & REPAIR	<b>SIZE:</b> 246mm x 352mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOUR:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Daming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> 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 RECOVER & REPAIR**

Each vegetable capsule contains:  
Devil's claw, Cannabidiol, Turmeric.  
Sugar Free.

**D 33.6 Western Herbal Medicine. Complementary Medicine: Discipline-Specific Traditional Claims.**

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.

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

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

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

**1. What BIOGEN CBD RECOVER & REPAIR is and what it is used for**

BIOGEN CBD RECOVER & REPAIR may assist to relieve joint pain associated with osteoarthritis and inflammation.

**2. What you need to know before you take BIOGEN CBD RECOVER & REPAIR****Do not take BIOGEN CBD RECOVER & REPAIR:**

- If you are hypersensitive (allergic) to Cannabidiol, Devil's Claw, Turmeric or any of the ingredients of BIOGEN CBD RECOVER & REPAIR (see section 6).
- If you are pregnant or breastfeeding your baby.

**Warnings and precautions**

- Use with caution if you have moderate or severe liver disease (hepatic impairment).
- Caution is advised if you suffer from gallstones, gastric-, duodenal- and stomach ulcers, bile duct obstruction, or excess stomach acid and are advised to discuss dosage requirements with your relevant healthcare provider.
- BIOGEN CBD RECOVER & REPAIR may cause delayed reactions, sedation and drowsiness.
- Patients who have had or had mood problems or depression should be monitored.
- Not recommended for use in children.

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

**Children and adolescents**

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

**Other medicines and BIOGEN CBD RECOVER & REPAIR**

Give your healthcare provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

It is advised to consult your doctor if you want to take BIOGEN CBD RECOVER & REPAIR combined with other medicines or treatments such as:

- Pain medication, such as methadone, as simultaneous use may cause additional adverse effects.
- Antiepileptic or anticonvulsant medication (such as brivaracetam, eslicarbazepine, rifinamide, 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.
- Simultaneous use of BIOGEN CBD RECOVER & REPAIR and 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.
- Central nervous system (CNS) depressants (for example barbiturates and benzodiazepines) 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.
- Simultaneous use may interfere with blood thinning medicines, like ticlopidine, warfarin, aspirin etc.

**BIOGEN CBD RECOVER & REPAIR and interactions with Diseases or Impairments**

- CBD may increase liver enzyme activity and in patients with liver disease or hepatic impairment.
- CBD may worsen symptoms associated with Parkinson disease.
- The possibility of excessive doses interfering with existing treatment for cardiac disorders or with hypo/hypertensive therapy should be considered.

**BIOGEN CBD RECOVER & REPAIR 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 RECOVER & REPAIR 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 RECOVER & REPAIR**

Do not share your medicines with any other person.

Always take BIOGEN CBD RECOVER & REPAIR 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 1 Capsule Daily. Each capsule contains 20 mg CBD. **Do not exceed the recommended maximum daily dose of 20 mg CBD.**

When discontinuing BIOGEN CBD RECOVER & REPAIR, the dose should be decreased gradually.

**If you take more BIOGEN CBD RECOVER & REPAIR 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 RECOVER & REPAIR with you so the doctor will know what you have taken.

**If you forget to take BIOGEN CBD RECOVER & REPAIR**

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

**4. Possible side effects**

BIOGEN CBD RECOVER & REPAIR can have side effects.

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

**Side effects associated with BIOGEN CBD RECOVER & REPAIR:**

**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.

Devil's Claw may cause allergic reactions, headaches, stomach upset, and acouphenes. Should your general health worsen or if you experience any untoward effects while taking BIOGEN CBD RECOVER & REPAIR, please consult your doctor, pharmacist or other healthcare provider 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 RECOVER & REPAIR.

**5. How to store BIOGEN CBD RECOVER & REPAIR**

- 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 CBD RECOVER & REPAIR contains**

Each capsule contains *Harpagophytum procumbens* (Devil's claw) 450,00 mg, *Cannabis sativa* L. (CBD isolate) 20,00 mg, and *Curcuma longa* (Turmeric) 10,00 mg.

The other ingredients are magnesium stearate and microcrystalline cellulose.

**What BIOGEN CBD RECOVER & REPAIR looks like and contents of the pack**

175 ml PET container with a Biogen lid. Packed in a unit carton.

BIOGEN CBD RECOVER & REPAIR is size 00 white vegetable capsules.

**Holder of certificate of registration**

Biogen,  
23 Stag Rd,  
Glen Austin,  
South Africa

**This pamphlet was last revised in July 2021.**

**Registration number**

Will be allocated by SAHPRA upon registration.

**PASIENTINLIGTINGSBLAD**SKEDULERINGSTATUS: **S0****BIOGEN CBD RECOVER & REPAIR**

Elke groentekapsule bevat:  
Duiwelsklou, Kannabidool, Borrie.

Suikervry.

**D 33.6 Westerse Kruid Medisyne. Komplementêre Medisyne: Dissipline-Spesifieke Tradisionele Bewerings.**

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

**Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.**

BIOGEN CBD RECOVER & REPAIR is beskikbaar sonder 'n dokter se voorskrif, sodat u jou gesondheid kan onderhou. U moet BIOGEN CBD RECOVER & REPAIR nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN CBD RECOVER & REPAIR met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteaker indien u verdere inligting of advies nodig het.

**Wat is in hierdie inligtingsblad**

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

**1. Wat is BIOGEN CBD RECOVER & REPAIR en waarvoor word dit gebruik**

BIOGEN CBD RECOVER & REPAIR, kan help om gewrigspyn, wat verband hou met osteoarthritis en inflammasie, te verlig.

**2. Wat jy moet weet voordat u BIOGEN CBD RECOVER & REPAIR neem****Moenie BIOGEN CBD RECOVER & REPAIR neem nie:**

- Indien u hipersensitief (allergies) is vir Kannabidool, Duiwelsklou, Borrie of vir enige van die bestanddele van BIOGEN CBD RECOVER & REPAIR (sien afdeling 6).
- Indien u swanger is of u baba borsvoed.

**Waarskuwings en voorsorgmaatreëls**

- Gebruik versigtig indien u ligte tot ernstige lewer probleme het.
- Gebruik versigtig in pasiënte met Parkinson-siekte.
- BIOGEN CBD RECOVER & REPAIR mag sedasie, vertraagde reaksies en lomerigheid veroorsaak.
- Pasiënte wat gemoedsprobleme of depressie het of gehad het, moet gemonteer word.
- Moet nie vir kinders toegedien word nie.

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

**Kinders en adolessente**

BIOGEN CBD RECOVER & REPAIR word nie vir kinders aanbeveel nie.

**Ander medisyne en BIOGEN CBD RECOVER & REPAIR**

Gee u gesondheidsorgverskaffer 'n lys van al die medisyne, kruid, nie-voorskrifmedisyne of voedingsaanvullings wat u gebruik.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN CBD RECOVER & REPAIR wil kombineer saam met ander medisyne of behandelinge soos:

- Pynmedikasie, soos metadon, omrede die gesamentlike gebruik addisionele nadelige gevolge kan veroorsaak.
- Anti-epileptiese of anti-convulsiewe medikasie (soos brivaracetam, eslicarbazepine, rifinamide, zonisamide, valproaat, topiramaat en stiripentol)
- Kan lei tot lewerskade as gevolg van verhoogde lewerensiem vlakke. Boonop mag valproaat ook lei tot 'n verlaagde bloedplaatjie telling.
- Gesamentlike gebruik van BIOGEN CBD RECOVER & REPAIR en voorbehoedmiddels mag interaksies veroorsaak. Indien 'n pasiënt gebruik maak van hormonale voorbehoeding en deurbraakbloeding ondervind, gaan addisionele voorbehoedmetodes toegepas moet word om ongewenste swangerskap te voorkom.
- Sentrale senuweestelsel (SSS) depressante (bv. zopikloon, diasepien, alprazolam, klobazam ens.), omdat die gesamentlike gebruik met CBD die risiko van sedasie en lomerigheid kan verhoog. Kruid/aanvullings met sederende eienskappe soos Kaliforniese papaver, katkruid, hop, Jamaican dogwood, kava, L-triptofaan, 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 nuwe-effekte vererger.
- Kinase inhibeerder, everolimus, omrede die gesamentlike gebruik die nuwe-effekte van everolimus kan vererger.
- Anti-retrovirale middels, antibiotika soos eritromisien en klaritromisien, antidepressante soos fluvoxamin, en proton pomp inhibeerders (PPI's) soos omeprasool, aangesien hierdie middels die plasma vlakke van CBD kan verhoog en sodoende die nuwe-effekte daarvan vererger.
- Fenobarbital, fenitoien, karbamasepien, prednisoon en rifampisien, omrede dit CBD plasma vlakke verlaag en gevolglik ook die effektiwiteit van CBD verminder.
- Gesamentlike gebruik kan die effektiwiteit van bloedverdunnende medisyne, soos tiklopidine, warfarin, aspirien, ens.

**BIOGEN CBD RECOVER & REPAIR en interaksies met siektes of gebreke**

- CBD kan ensiemaktiwiteit in die lewer verhoog by pasiënte met lewersiekte of lewersversaking.
- CBD kan simptome in pasiënte met Parkinson-siekte vererger.
- Die moontlikheid van oormatige dosisse wat inmeng met die bestaande behandeling vir hartafwykings of met hipo/hipertensiewe terapie moet oorweeg word.

**BIOGEN CBD RECOVER & REPAIR 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 kalmering en slaperigheid 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, apteaker of gesondheidsorgwerker voordat u hierdie medisyne gebruik.

**Bestuur en die gebruik van masjiene**

Geen studies is uitgevoer oor die uitwerking op die vermoë om te bestuur of masjinerie te gebruik nie. Dit is moontlik dat BIOGEN CBD RECOVER & REPAIR die vermoë om te bestuur of gebruik van masjinerie beïnvloed, aangesien CBD vertraagde reaksies, slaperigheid 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 RECOVER & REPAIR te neem**

Moenie jou medisyne met enigiemand anders deel nie.

Neem BIOGEN CBD RECOVER & REPAIR altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteaker vir jou aangewys het. Vra gerus jou dokter of apteaker indien jy onseker is.

**Volwassenes:** Neem 1 Kapsule Daaglik. Elke kapsule bevat 20 mg CBD. **Moenie die aanbevole maksimum daaglikse dosis van 20 mg CBD oorskry nie.**

As u die BIOGEN CBD RECOVER & REPAIR staak, moet die dosis geleidelik verminder word.

**Wat om te doen indien jy meer BIOGEN CBD RECOVER & REPAIR geneem het as wat jy moet**

Geen bekende informasie. In die geval van 'n oordosis, raadpleeg jou dokter of apteaker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BIOGEN CBD RECOVER & REPAIR saam sodat die dokter kan sien wat jy ingeneem het.

**Indien jy vergeet om BIOGEN CBD RECOVER & REPAIR te neem**

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

**4. Moontlike nuwe-effekte**

BIOGEN CBD RECOVER & REPAIR kan nuwe-effekte hê.

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

**Nuwe-effekte geassosieer met CBD:**

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

**Algemeen:** Lomerigheid, verdouing, vertraagde reaksies, lusteloosheid, duiseligheid en moegheid.

**Frekvensie onbekend:** Verhoogde lewerensiem.

Raadpleeg u dokter of apteaker vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN CBD RECOVER & REPAIR neem.

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

**Rapportering van nuwe-effekte**

Indien jy nuwe-effekte ondervind, bespreek dit met u dokter of apteaker. U kan ook nuwe-effekte aan SAHPRA rapporteer via die **Adverse Drug Reactions Reporting Form**, te rapporteer, wat aanlyn 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 CBD RECOVER & REPAIR te verskaf.

**5. Hoe om BIOGEN CBD RECOVER & REPAIR 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 jou apteaker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

**6. Inhoud van die pak en ander inligting****Wat BIOGEN CBD RECOVER & REPAIR bevat**

Elke kapsule bevat *Harpagophytum procumbens* (Duiwelsklou) 450,00 mg, *Cannabis sativa* L. (Isolaat) 20,00 mg, en *Curcuma longa* (Borrie) 10,00 mg.

Die ander bestanddele is magnesiumstearaat en mikrokristalliene sellulose.

**Hoe BIOGEN CBD RECOVER & REPAIR lyk en inhoud van die verpakking**

175 ml PET-houer met 'n Biogen-deksel. Verpak in 'n karton.

BIOGEN CBD RECOVER & REPAIR is grootte 00 wit groentekapsules.

**Houer van die registrasiesertifikaat**


Biogen,  
Stag Weg 23,  
Glen Austin,  
Suid Afrika

**Hierdie inligtingsblad is laas hersien in**

Julie 2021.

**Registrasienuommer**

Sal met registrasie deur SAHPRA toegeken word.

<b>JOB:</b> BPS_CBD RECOVER & REPAIR	<b>SIZE:</b> 246mm x 352mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="checked" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOUR:</b> 	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doring <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b>	Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.