

PROFESSIONAL INFORMATION RELEAF CBD STRESS CAPSULES

D 34.13 Other. Complementary Medicine. Health Supplement.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: **S0**

1. NAME OF MEDICINE:
RELEAF CBD Stress Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each **RELEAF CBD Stress Capsule** contains 125 mg L-Theanine, 8,3 mg *Cannabis sativa* L. cannabidiol (CBD isolate) and 1,10 % Terpenes (Limonene, β -Caryophyllene, Humulene and Myrcene).
Free of Sucrose and Glucose. For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsules (30's)
Pink gelatine capsules.

4. CLINICAL PARTICULARS:
4.1 Therapeutic Indications
RELEAF CBD Stress Capsules supports relaxation, health maintenance¹ and enhancement¹, and is used to assist with the relief of restlessness,² sleeplessness³ and anxiousness.⁴⁻⁶
RELEAF CBD Stress Capsules is indicated for adults 18 years and older.

4.2 Posology and method of administration
Posology
Adults (18 years and older)
Take one to two capsules maximum per day in single or divided doses.
Do not exceed the recommended maximum daily dose of 20 mg CBD.

Method of administration
Take **RELEAF CBD Stress Capsules** orally.

4.3 Contraindications
• Hypersensitivity to cannabidiol⁷, limonene⁸, soybean⁹, hops¹⁰, theanine or other excipients listed under section 6.1.
• Contraindicated in patients with hypotension.⁶
• Not to be given to children (see section 4.8 d).

4.4 Special warnings and precautions for use
The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes.⁷
Patients who have or had mood problems or depression should be monitored.⁷
CBD may cause psychomotor slowing, sedation and somnolence.⁷
Theanine may have a hypotensive effect.⁶
Contains allergens: Limonene⁸, soybean⁹ and hops.¹⁰

4.5 Interaction with other medicines and other forms of interaction
Interactions with Medicines
Antiepileptic/anticonvulsant medication: The concomitant use of CBD and antiepileptic/anticonvulsant medication (such as brivaracetam, eslicarbazepine, rifinamide, zonisamide and valproate) could increase antiepileptic drug plasma levels and elevate liver transaminases.^{2,7} In addition, valproate may also result in low blood platelet count.²
Central nervous system (CNS) depressants: Concomitant use of CBD with central nervous system (CNS) depressants (for example barbiturates and benzodiazepines) may increase the risk of sedation and somnolence.^{2,11}

Strong inhibitors of CYP3A4 or CYP2C19: Co-administration with moderate or strong inhibitors of CYP3A4 or CYP2C19 may increase CBD plasma concentrations, which may lead to a greater risk of side effects.^{2,7} This includes antiretroviral medication like protease inhibitors, antibiotics like erythromycin and clarithromycin, selective serotonin reuptake inhibitors (SSRI's) like fluvoxamine and proton pump inhibitors (PPI) like omeprazole.

Strong inducers of CYP3A4 or CYP2C19: Co-administration with strong inducers of CYP3A4 or CYP2C19 may decrease CBD plasma concentrations, which may lower the efficacy of CBD-containing products.^{2,7} This includes phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin.

Kinase inhibitors: Concomitant use of CBD and everolimus (kinase inhibitor) may cause additive adverse effects.²

Immunosuppressants: Co-administration of immunosuppressants (such as tacrolimus and cyclosporine) and CBD may result in elevated immunosuppressant plasma levels and consequently additive adverse effects.²

Antihypertensive drugs: Concomitant use of theanine and antihypertensive drugs (such as captopril, enalapril, losartan and valsartan) may have an additive blood pressure lowering effect.⁶

Stimulant drugs: Co-administration of theanine and stimulant drugs (such as dextroamphetamine, epinephrine and phentermine) may decrease the effectiveness of stimulant drugs.⁶

Caffeine-containing supplements: Theanine acts as a caffeine antagonist and may inhibit the stimulant effects produced by caffeine supplements such as coffee, guarana and others.⁶

Interactions with Diseases/Impairments
Hepatic impairment: The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes⁷ (see section 4.4).
Hypotension: Theanine may lower blood pressure.⁶

Interactions with Foods
Fats: As CBD is highly lipophilic, it dissolves easily in the fat content of food. Thus, the concomitant consumption of CBD and high fatty food may increase the solubility, absorption and bioavailability of CBD.¹²
Alcohol: Do not take with alcohol as it may increase the risk of sedation and somnolence.⁷

4.6 Fertility, pregnancy and lactation
Not recommended for use during pregnancy and lactation.¹¹
Effects of **RELEAF CBD Stress Capsules** on human fertility is unknown.

4.7 Effects on ability to drive and use machines
RELEAF CBD Stress Capsules may affect the ability to drive or operate machinery, as it may cause psychomotor slowing⁷, somnolence^{6,7} and sedation.⁷ Please exercise care until you are certain that your ability to perform such activities is not affected.

4.8 Undesirable effects
4.8 a Summary of safety profile
CBD², terpenes¹³ and theanine⁶ are generally well tolerated.

4.8 b Summary of adverse reactions
Gastrointestinal disorders (Frequent): Dry mouth², weight loss, diarrhoea, vomiting, decreased appetite and abdominal pain or discomfort.⁷
Nervous system disorders (Frequent): Somnolence, sedation, psychomotor slowing, lethargy, dizziness and fatigue.⁷

Nervous system disorders (Frequency unknown): Headache.⁶
Investigations (Frequency unknown): Elevated liver transaminases.⁷

4.8 c 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.⁷ Dizziness is mostly reported when CBD is concomitantly used with clobazam, a benzodiazepine.⁷ Elevated liver transaminases mostly appears in patients with baseline elevated liver enzymes or in patients who concomitantly consume valproate or clobazam.⁷ Discontinuation or dose adjustment of valproate or clobazam is recommended if elevated liver transaminases are detected.

4.8 d Paediatric Population
RELEAF CBD Stress Capsules is not recommended for use in children.

4.8 e Other special populations
No clinical data are available on the effects of **RELEAF CBD Stress Capsules** on other special populations.

4.9 Overdose
No known side effects were reported for overdose of CBD^{7,14}, terpenes or theanine. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:
5.1 Pharmacodynamic properties
Mechanism of action:
CBD can interact or alter the endocannabinoid signalling pathways (via the cannabinoid receptors)¹⁵ and the non-endocannabinoid pathways (interactions with serotonin 5-HT1A receptors, GPR55 receptors and vanilloid-1 receptors).¹⁶ CBD also inhibits the degradation of the endocannabinoid, anandamide, which may contribute to its antipsychotic effects.¹⁶ Cannabinoids and terpenes interact synergistically, increasing the therapeutic index of cannabinoids, a process known as the entourage effect.¹⁷

Theanine acts as a gamma-aminobutyric acid (GABA) agonist, consequently increasing GABA levels in the brain, which promotes relaxation. In addition, theanine stimulates alpha wave production in the brain, leading to mental alertness and relaxation.⁶

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.¹¹

Limonene: Cyclic monoterpene with immune potentiator, antidepressant and antimutagenic properties.¹⁸
 β -Caryophyllene: Bicyclic sesquiterpene with anti-inflammatory, anticarcinogenic, antimicrobial, antioxidative, and analgesic properties.¹⁹

Humulene: Monocyclic sesquiterpene with analgesic, antibacterial, anti-inflammatory and antiproliferative properties.¹⁸
Myrcene: Monoterpene with analgesic, anti-inflammatory, antibiotic and antimutagenic properties.¹⁸

Theanine: A natural amino acid that helps to support and temporarily promotes relaxation. It supports the maintenance of healthy sleep and acts as an caffeine antagonist.⁶

5.2 Pharmacokinetic properties
Absorption: Oral bioavailability of CBD is very low (13 % - 19 %). This can be ascribed to first pass metabolism.¹²
Terpene absorption is rapid and starts in the oral cavity.²⁰
Theanine is absorbed through the intestines.⁶

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.²¹ CBD and its metabolites are more than 94 % protein bound.²
The distribution of terpenes is unknown.

Once absorbed, theanine is distributed to the plasma and erythrocytes. It also has the ability to cross the blood brain barrier.⁶
Metabolism: CBD is vastly metabolized in the liver.²¹ It undergoes hydroxylation, oxidation, beta-oxidation, conjugation, and epoxidation.²
Terpenes are metabolized through cytochrome P450.²⁰

Theanine is hydrolyzed in the intestines to glutamic acid and ethylamine. It's half-life plasma elimination ranges from 0,8 - 1,2 hours.⁶
Excretion: The half-life of CBD is between 56 to 61 hours.⁷ CBD is excreted in the faeces, with minor renal clearance.⁷ Terpenes are excreted as conjugated metabolites by the kidneys.²⁰
Theanine and its metabolites are mostly excreted in the urine.⁶

5.3 Preclinical safety data
When used orally and appropriately in adults, CBD is recognized as possibly safe.² Terpenes¹³ are proven safe. Theanine is considered possibly safe when used orally and appropriately, short-term.⁶

6. PHARMACEUTICAL PARTICULARS:
6.1 List of excipients
• α -Tocopheryl acetate (Vitamin E)
• *Cannabis sativa* L. cannabigerol (CBG isolate)
• Colloidal silicon dioxide
• *Glycine max* L. Merr. (Lecithin) oil
• *Humulus lupulus* L. (Hops flower powder)
• Magnesium stearate
• Medium chain triglyceride (MCT) oil
• Microcrystalline cellulose

6.2 Incompatibilities
In the absence of compatibility studies, **RELEAF CBD Stress Capsules** must not be mixed with other medicines.

6.3 Shelf life
23 months

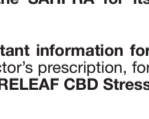
6.4 Special precautions for storage
Store in a cool, dry place at or below 25 °C.
Do not use after expiry date.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents
RELEAF CBD Stress Capsules: 30's: Pink gelatine size 0 capsules are available in PVDC/aluminium blister strips, with each blister strip containing 10 capsules. Each carton of 30 capsules contains 3 blister strips.

6.6 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
RELEAF PHARMACEUTICALS (PTY) LTD
14 De Vreugde Crescent
Dal Josaphat
Paarl
7646

Tel: +27 (21)001 9748
Email: info@releafpharma.co.za



8. REGISTRATION NUMBER(S)
To be allocated.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Not Applicable

10. DATE OF REVISION OF THE TEXT
July 2020

RP9041/20A

PATIENT INFORMATION LEAFLET RELEAF CBD STRESS CAPSULES

SCHEDULING STATUS: **S0**

RELEAF CBD Stress Capsules

Cannabidiol/Terpenes/L-Theanine
8,3 mg/1,10 %/125 mg
Free of Sucrose and Glucose

D 34.13 Other. Complementary Medicine. Health Supplement.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you. **RELEAF CBD Stress Capsules** is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **RELEAF CBD Stress Capsules** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **RELEAF CBD Stress Capsules** with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet
1. What is **RELEAF CBD Stress Capsules** and what it is used for
2. What you need to know before you take **RELEAF CBD Stress Capsules**
3. How to take **RELEAF CBD Stress Capsules**
4. Possible side effects
5. How to store **RELEAF CBD Stress Capsules**
6. Contents of the pack and other information

1. What RELEAF CBD Stress Capsules is and what it is used for
RELEAF CBD Stress Capsules supports relaxation, health maintenance¹ and enhancement¹, and is used to assist with the relief of restlessness,² sleeplessness³ and anxiousness.⁴⁻⁶

2. What you need to know before you take RELEAF CBD Stress Capsules
Do not take RELEAF CBD Stress Capsules:
• If you are hypersensitive (allergic) to cannabidiol⁷, limonene⁸, soybeans⁹, hops¹⁰, theanine or to any of the other ingredients in **RELEAF CBD Stress Capsules** (listed in section 6).
• If you have low blood pressure.⁶
• If you are pregnant or breastfeeding your baby.¹¹
• Not to be given to children.

Warnings and Precautions
Use with caution if you have mild or severe hepatic impairment (liver disease).⁷
Patients who have or had mood problems or depression should be monitored.⁷
CBD may cause delayed reactions, sedation and drowsiness.⁷
Theanine may have a hypotensive effect.⁶
Contains allergens: Limonene⁸, soybean⁹ and hops.¹⁰

Children and adolescents
RELEAF CBD Stress Capsules is not recommended for use in children.

Other medicines and RELEAF CBD Stress Capsules
Always tell your healthcare provider if you are taking other medicines, including complementary or traditional medicines.
Consult your doctor if you want to take **RELEAF CBD Stress Capsules** in combination with medicines or treatments such as:

- Antiepileptic or anticonvulsant medication (such as brivaracetam, eslicarbazepine, rifinamide, zonisamide and valproate) since concomitant use could result in liver damage due to elevated liver enzymes.⁷ In addition, valproate may also result in low blood platelet count.²
- Central nervous system depressants (zopiclone, diazepam, alprazolam, clobazam etc.) as it may increase the risk of sedation and drowsiness.^{2,11}
- Antiretroviral medication, antibiotics like erythromycin and clarithromycin, antidepressants like fluvoxamine and proton pump inhibitors (PPI) like omeprazole, since these might increase CBD plasma concentrations leading to a greater risk of side effects.⁷
- Phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin, as it will decrease CBD plasma concentrations, which may lower the efficacy of CBD-containing products.⁷

- Kinase inhibitor, everolimus, as co-administration may cause additive adverse effects.²
- Immunosuppressants (such as topiramate and tacrolimus) as concomitant use may result in elevated immunosuppressant plasma levels and consequently additive side effects.²
- Antihypertensive drugs, as the concomitant use of theanine and antihypertensive drugs (such as captopril, enalapril, losartan and valsartan) may have an additive blood pressure lowering effect.⁶
- Stimulant drugs, as the co-administration of theanine and stimulant drugs (such as diethylpropion, ephedrine and phentermine) may decrease the effectiveness of stimulant drugs.⁶
- Caffeine-containing supplements, as theanine acts as a caffeine antagonist and may inhibit the stimulant effects produced by caffeine supplements such as coffee, guarana and others.⁶

RELEAF CBD Stress Capsules with food and drink

Take **RELEAF CBD Stress Capsules** with a meal high in fat for optimal CBD absorption and bioavailability.¹²
Do not take **RELEAF CBD Stress Capsules** with alcohol as it may increase the risk of sedation and drowsiness.⁷

Pregnancy and breastfeeding

Not recommended for use during pregnancy and lactation.¹¹
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 this medicine.

Driving and using machines

It is not always possible to predict to what extent **RELEAF CBD Stress Capsules** may interfere with the daily activities of a patient. It is possible that **RELEAF CBD Stress Capsules** would affect the ability to drive or operate machinery, as CBD may cause delayed reactions⁷, drowsiness^{6,7} and sedation.⁷ Patients should ensure that they do not engage in the above activities until they are aware of the extent to which **RELEAF CBD Stress Capsules** affects them.

3. How to take RELEAF CBD Stress Capsules

Do not share medicines prescribed for you with any other person.
Always take **RELEAF CBD Stress Capsules** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Adults (18 years and older)

Take one to two capsules maximum per day in single or divided doses.
Do not exceed the recommended maximum daily dose of 20 mg CBD.

If you take more RELEAF CBD Stress Capsules than you should

No known information.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take RELEAF CBD Stress Capsules

Always take **RELEAF CBD Stress Capsules** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

RELEAF CBD Stress Capsules can have side effects.
Not all side effects reported for **RELEAF CBD Stress Capsules** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **RELEAF CBD Stress Capsules**, please consult your healthcare provider for advice.

Side effects associated with CBD and theanine:

Frequent:

- Dry mouth², diarrhoea, vomiting, decreased appetite, weight loss and abdominal pain or discomfort.⁷
- Drowsiness, sedation, delayed reactions, lethargy, dizziness and fatigue.⁷

Frequency unknown:

- Elevated liver enzymes (transaminases)⁷ and headache.⁶

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **RELEAF CBD Stress Capsules**.

5. How to store RELEAF CBD Stress Capsules

Store in a cool, dry place at or below 25 °C.
Do not use after expiry date.
Protect from light.
STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Return all unused **RELEAF CBD Stress Capsules** to your pharmacist. Do not dispose of unused **RELEAF CBD Stress Capsules** in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RELEAF CBD Stress Capsules contains

Active ingredients per capsule are L-Theanine, *Cannabis sativa* L. cannabidiol (CBD isolate) and Terpenes (Limonene, β-Caryophyllene, Humulene and Myrcene).
The other ingredients are: α-Tocopheryl acetate (Vitamin E), *Cannabis sativa* L. cannabigerol (CBG isolate), Colloidal silicon dioxide, *Glycine max* L. Merr. (Lecithin) oil, *Humulus lupulus* L. (Hops flower powder), Magnesium stearate, Medium chain triglyceride (MCT) oil and Microcrystalline cellulose.
Contains allergens: Limonene⁸, soybean⁹ and hops.¹⁰

What RELEAF CBD Stress Capsules looks like and contents of the pack

RELEAF CBD Stress Capsules: 30's: Pink gelatine size 0 capsules are available in PVDC/aluminium blister strips, with each blister strip containing 10 capsules. Each carton of 30 capsules contains 3 blister strips.

Holder of Certificate of Registration and Manufacturer

RELEAF PHARMACEUTICALS (PTY) LTD
14 De Vreugde Crescent
Paarl
7646

Tel: +27 (21)001 9748

Email: info@releafpharma.co.za

This leaflet was last revised in

July 2020

RP9042/20A

PASIËNTINLIGTINGSBLAD RELEAF CBD STRESS CAPSULES

SKEDULERINGSSTATUS: S0

RELEAF CBD Stress Capsules

Kannabidiol/Terpene/L-Teaniën
8,3 mg/1,10 %/125 mg
Vry van Sukrose en Glukose

D 34.13. Ander. Komplementêre Medisyne. Gesondheidsaanvulling.

Hierdie ongeregistreerde medisyne is nie deur die Sahpra geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. RELEAF CBD Stress Capsules is beskikbaar sonder 'n dokter se voorskrif om u gesondheid te ondersteun. U moet egter steeds **RELEAF CBD Stress Capsules** versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie **RELEAF CBD Stress Capsules** met enige ander persoon deel nie.
- Indien u verdere inligting of advies verlang, vra asseblief u gesondheidsorgwerker of apteker.
- U moet 'n dokter raadpleeg indien u simptome vererger of nie verbeter nie.

Wat is in hierdie vouiljet

1. Wat **RELEAF CBD Stress Capsules** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **RELEAF CBD Stress Capsules** neem
3. Hoe om **RELEAF CBD Stress Capsules** te neem
4. Moontlike nuwe-effekte
5. Inhoud van **RELEAF CBD Stress Capsules** te stoor
6. Inhoud van die verpakking en ander inligting

1. Wat RELEAF CBD Stress Capsules is en waarvoor dit gebruik word

RELEAF CBD Stress Capsules ondersteun die instandhouding en verbetering van ontspanning, gesondheid en help met die verligting van rusteloosheid, slapeloosheid en angstigheid.

2. Wat u moet weet voordat u RELEAF CBD Stress Capsules neem

Moet nie RELEAF CBD Stress Capsules neem nie:

- Indien u hipersensitief (allergies) is vir kannabidiol, limonee, sojaboon, hop, teaniën of enige van die ander bestanddele in **RELEAF CBD Stress Capsules** (gelys in afdeling 6).
- Indien u lae bloeddruk het.
- Indien u swanger is of u baba borsvoed.
- Moet nie vir kinders toegedien word nie.

Waarskuwings en voorsorgmaatreëls

Gebruik versigtig indien u ligte tot ernstige lewer probleme het.
Pasiënte wat gemoedsprobleme of depressie het of gehad het, moet gemonitor word.
CBD mag sedasie, vertraagde reaksies en lomerigheid veroorsaak.

Teaniën mag 'n bloeddrukverlagende effek hê.
Bevat allergene: Limonee, sojaboon en hop.

Kinders en adolessente

RELEAF CBD Stress Capsules word nie vir kinders aanbeveel nie.

Ander medikasie en RELEAF CBD Stress Capsules

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

Raadpleeg u dokter as u **RELEAF CBD Stress Capsules** in kombinasie met die volgende medisyne wil gebruik:

- Anti-epileptiese medikasie (soos brivaracetam, eslicarbazepien, rufinamid, zonisamied en valproaat) aangesien die kombinasie kan lei tot lewerskade weens verhoogde transaminasie ensiem vlakke in die lewer. Boonop mag valproaat ook lei tot 'n verlaagde bloedplaatjie telling.
- Sentrale senuweestelsel depressante (bv. zopikloon, diasepien, alprazolam, klobazam ens.), omdat die gesamentlike gebruik met CBD die risiko van sedasie en lomerigheid kan verhoog.
- Anti-retrovirale middels, antibiotika, soos eritromisin en klaritromisin, antidepressante soos fluvoxamien, en proton inhibeerders (PPI) soos omeprazol, 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.
- Kinase inhibeerder, everolimus, omrede die gesamentlike gebruik die nuwe-effekte van everolimus kan vererger.
- Immuunonderdrukkers (soos topiramate en takrolimus), omrede die gesamentlike gebruik die vlakke van hierdie onderdrukkers in die plasma kan verhoog en gevolglik die nuwe-effekte vererger.
- Anti-hipertensiewe middels, omrede die gesamentlike gebruik van teaniën en anti-hipertensiewe middels (soos captopril, enalapril, losartan en valsartan) 'n adisionele bloeddrukverlagende effek kan hê.
- Stimuleer middels, omrede die gesamentlike gebruik van teaniën en stimuleer middels (soos diethylpropion, ephedrien en phentermien) die effektiwiteit van hierdie middels kan beïnvloed.
- Kafieienbevattende aanvullings, omrede teaniën as 'n kafeïenantagonis optree en die stimulerende effekte van kafeïenaanvullings soos koffie, guarana en ander kan beïnvloed.

RELEAF CBD Stress Capsules met kos en drinkgoed

Neem **RELEAF CBD Stress Capsules** met 'n maaltyd hoog in vet vir optimale CBD opname en biobeskikbaarheid.

Die gesamentlike inname van alkohol en **RELEAF CBD Stress Capsules** mag sedasie en lomerigheid veroorsaak.

Swangerskap en borsvoeding

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

Nie alle nuwe-effekte wat aangemeld is vir **RELEAF CBD Stress Capsules** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Dit is moontlik dat **RELEAF CBD Stress Capsules** die vermoë om te bestuur of masjinerie te gebruik sal beïnvloed, deur dat CBD vertraagde reaksies, sedasie en lomerigheid kan veroorsaak. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle nie bewus is van hoe **RELEAF CBD Stress Capsules** hulle beïnvloed nie.

3. Hoe om RELEAF CBD Stress Capsules te neem

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem **RELEAF CBD Stress Capsules** soos voorgeskryf in hierdie vouiljet of soos u dokter of apteker u aanbeveel het.

Maak asseblief seker by u dokter of apteker wat die aanbevole dosis is indien u onseker is.

Volwassenes (18 jaar en ouer)

Neem maksimum een tot twee kapsules per dag in enkel of verdeelde dosisse.
Moet nie die aanbevole maksimum daaglikse dosis van 20 mg CBD oorskry nie.

Indien u meer RELEAF CBD Stress Capsules geneem het as wat u moes

Geen bekende informasie.
In die geval van 'n overdosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om RELEAF CBD Stress Capsules te neem

Neem **RELEAF CBD Stress Capsules** altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit so gou as wat u onthou. Indien u egter nie van 'n dosis onthou voordat dit tyd is vir die volgende dosis nie, slaan die vergete dosis oor en keer terug na u gewone dosieringskedule. Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

4. Moontlike nuwe-effekte

RELEAF CBD Stress Capsules kan nuwe-effekte hê.

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

Algemene

- Droë mond, diarree, braking, verlaagde eetlus, gewigsverlies en abdominale pyn en -ongemak.
- Lomerigheid, sedasie, vertraagde reaksies, duisligheid en moegheid.

Frekwensie onbekend

- Verhoogde lewerensiem (transaminases) en kopseer.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker indien u nuwe-effekte ervaar. Dit sluit in enige moontlike nuwe-effekte wat nie in hierdie vouiljet gelys is nie. U kan ook nuwe-effekte by die Sahpra aanmeld via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder Sahpra se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting rakende die veiligheid van **RELEAF CBD Stress Capsules** te verskaf.

5. Hoe om RELEAF CBD Stress Capsules te stoor

Bewaar in 'n koel, droë plek by of benede 25 °C.
Moet nie na die vervaldatum gebruik nie.
Beskerm teen lig.
HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

Neem alle ongebruikte **RELEAF CBD Stress Capsules** na u apteker terug.
Moenie ongebruikte **RELEAF CBD Stress Capsules** in afvoertyppe of rioolsisteme (byvoorbeeld toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat RELEAF CBD Stress Capsules bevat
Aktiewe bestanddele per kapsule is L-Teaniën, *Cannabis sativa* L. kannabidiol (CBD isolaat) en Terpene (Limonene, β-Kariofilien, Humuleen en Mirseen).

Die ander bestanddele is: α-Tokoferielasetaat (Vitamiën E), *Cannabis sativa* L. kannabigerol (CBG isolaat), *Glycine max* L. Merr. (Lesitiën) olie, *Humulus lupulus* L. (Hop blompoelier), Kolloïdale silikondioksied, Magnesiumstearaat, Medium ketting triglyseried (MKT) olie en Mikrokrystallyne sellulose.

Bevat allergene: Limonee, sojaboon en hop.

Hoe RELEAF CBD Stress Capsules lyk en die inhoud van die verpakking

RELEAF CBD Stress Capsules: 30's: Pienk grootte 0 gelatien kapsules is beskikbaar in PVDC/aluminium stolpverpakking, met elke stolpverpakking wat 10 kapsules bevat. Elke dosie van 30 kapsules bevat 3 stolpverpakings.

Houer van registrasie en vervaardiger

RELEAF PHARMACEUTICALS (PTY) LTD
14 De Vreugde Crescent
Paarl
7646

Tel: +27 (21)001 9748

Epos: info@releafpharma.co.za

Hierdie vouiljet was laaste hersien in

Julie 2020

RP9042/20A

Pro-Print



PRO-PRINT (PTY) LTD

THE PROFESSIONALS IN PRINT

REPRO

Date: 13th August 2020
Operator: Aaron Sudree
Customer: Afriplex
Product Name: Realeaf CBD Stress Caps PI/PIL
Product Code: PI RP9041/20A PIL RP9042/20A
Dimensions: 100 x 760 mm
Fold Size: 100 x 33 mm
Font Size: 6 point Times
Colours: (1) Black
--
Barcode: --
Pharmacode: (Ref. 41) 10101
Stock: 40 gsm Pro-Thin
Proof Status: 1st (First)

Proof read by:

Reset: Alterations: Disk/Possie:

No alterations – proceed as soon as possible

Note alterations – Further proof is required

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature: *Rautenbach* Date: 13-08-20

PROOF NOT READ – NO COPY SUPPLIED