

## PROFESSIONAL INFORMATION

# CANNISOL DAILY CAPSULES

D 34.13 Other. Complementary Medicine. Health Supplement.

Health supplements are intended only to complement health or supplement the diet.

**This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.**

**SCHEDULING STATUS:** [S0]

### 1. NAME OF MEDICINE:

**CANNISOL DAILY CAPSULES 10 mg** (capsules)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each capsule contains 10 mg *Cannabis sativa* L. cannabidiol (CBD) isolate.

Sugar free

Contains allergen: Soy lecithin

For the full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Capsules (60's)

White, size 0 vegetable capsules

### 4. CLINICAL PARTICULARS:

#### 4.1 Therapeutic Indications

**CANNISOL DAILY CAPSULES** is made from pure, high quality ingredients and contains Cannabidiol (CBD). It may help the body's natural responses to anxiousness,<sup>1,2</sup> pain and inflammation.<sup>3-6</sup>

**CANNISOL DAILY CAPSULES** is indicated for adults 18 years and older.

#### 4.2 Posology and method of administration

##### Posology

##### **Adults (18+)**

Take 1-2 capsules daily, preferably with a meal or as directed by your healthcare practitioner.

**DO NOT EXCEED THE DAILY RECOMMENDED DOSAGE OF 20 MG CBD.**

##### Method of administration

Take **CANNISOL DAILY CAPSULES** orally.

#### **Special populations**

##### Hepatic impairment

The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes.<sup>7,8</sup>

This increase appears to be dose-dependent, and more commonly observed in patients with baseline transaminase elevations or in patients already taking valproic acid (anticonvulsant) or clobazam (benzodiazepine).<sup>8</sup>

Thus, a lower cannabidiol starting dose is recommended in patients with hepatic impairment.<sup>8</sup>

##### Elderly

Elderly individuals may be more sensitive to medicine acting on the central nervous system (CNS). Adverse reactions seem to be dose dependent. Additional studies are required to evaluate the safety and tolerability of cannabinoids in elderly populations.<sup>6</sup>

#### **Paediatric/Adolescent population**

The endocannabinoid system plays a significant role in the development of the nervous system *in utero* and during adolescence.<sup>6</sup> **CANNISOL DAILY CAPSULES** is not recommended for use in children or adolescents below 18 years of age.

#### 4.3 Contraindications

- Hypersensitivity to cannabidiol<sup>7</sup> or other excipients listed under section 6.1.
- Not recommended in women of childbearing age, those planning pregnancy, and those who are pregnant, or breastfeeding.<sup>6,8</sup>

#### 4.4 Special warnings and precautions for use

- Use with caution in patients with moderate or severe hepatic impairment as CBD may cause an increase in liver enzymes.<sup>7,8</sup>
- Use with caution in patients with Parkinson disease.<sup>8</sup>
- Patients who have or had mood problems or depression should be monitored.<sup>7</sup>
- CBD may cause psychomotor slowing, sedation and somnolence.<sup>7</sup>
- Contains allergen: Soy lecithin
- Avoid use in children or adolescents below 18 years of age (see section 4.8 d).

#### 4.5 Interaction with other medicines and other forms of interaction

##### Interactions with medicines

*Analgesics:* Methadone levels and its adverse effects may theoretically increase when using concomitantly with CBD.<sup>8</sup>

*Antiepileptics/anticonvulsants:* Concomitant use of CBD and antiepileptics/anticonvulsants such as brivaracetam, eslicarbazepine, rufinamide, stiripentol, topiramate, valproate, carbamazepine, and zonisamide, may increase antiepileptic/anticonvulsant plasma levels and elevate liver transaminases.<sup>7,8</sup>

*Anticoagulants:* CBD may elevate warfarin levels, consequently increasing the risk of bleeding.<sup>8</sup> In addition, increased valproate may also result in increased bleeding due to low blood platelet count.<sup>8</sup>

*Anti-estrogens:* Chronic use of CBD may theoretically reduce tamoxifen's active metabolites.<sup>8</sup>

*Antimanic agents:* CBD may theoretically cause lithium toxicity when using concomitantly.<sup>8</sup>

*Birth control medication:* Although speculated, it is unknown whether any clinically significant interactions exist between the concomitant use of CBD and hormonal contraceptives. If a female patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.<sup>9-12</sup>

*Caffeine:* CBD may increase caffeine levels when using concomitantly.<sup>8</sup>

*Central nervous system (CNS) depressants:* Concomitant use of CBD with CNS depressants, such as barbiturates and benzodiazepines, may increase the risk of sedation and somnolence.<sup>6,8</sup> Herbs/supplements with sedative properties, such as calamus, California poppy, catnip, hops, Jamaican dogwood, kava, L-tryptophan, melatonin, sage, St. John's wort, saffron, skullcap, and other may theoretically also have additive sedative properties when using concomitantly with CBD.<sup>8</sup>

*Glucuronidated agents:* CBD may increase the level of certain glucuronidated agents when using concomitantly.<sup>8</sup>

*Immunosuppressants:* Concomitant use of immunosuppressants (such as tacrolimus and sirolimus) and CBD may result in elevated immunosuppressant plasma levels and consequently additive adverse effects.<sup>8</sup>

*Kinase inhibitors:* Concomitant use of CBD and everolimus (kinase inhibitor) may increase everolimus levels causing additive adverse effects.<sup>8</sup>

*Strong inhibitors of CYP3A4 or CYP2C19:* Co-administration with moderate or strong inhibitors of CYP3A4 or CYP2C19 may increase CBD plasma concentrations, which may increase the risk of side effects.<sup>7,8</sup> These inhibitors include antiretroviral medication like protease inhibitors, antibiotics like erythromycin and clarithromycin, selective serotonin reuptake inhibitors (SSRI's) like fluvoxamine and proton pump inhibitors (PPI's) 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.<sup>7,8</sup> These inducers include phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin.

##### Interactions with diseases/impairments

*Hepatic impairment:* The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes.<sup>7</sup>

*Parkinson disease:* CBD may worsen symptoms associated with Parkinson disease<sup>8</sup> (see section 4.4).

##### Interactions with foods

*Alcohol:* Concomitant use of CBD and alcohol may increase the risk of sedation and somnolence.<sup>7</sup>

*Caffeine:* CBD may increase caffeine levels.<sup>8</sup>

*Fats:* CBD is highly lipophilic and 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.<sup>13</sup>

#### 4.6 Fertility, pregnancy and lactation

*Fertility:* High dosages of cannabidiol may damage the reproductive system of male offspring.<sup>6,8</sup>

*Pregnancy and lactation:* Not recommended for use during pregnancy and lactation.<sup>8</sup>

#### 4.7 Effects on ability to drive and use machines

CBD may affect the ability to drive or operate machinery, as it may cause psychomotor slowing, somnolence and sedation.<sup>7</sup> 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

Orally, CBD<sup>8</sup> is generally well tolerated.

### 4.8 b Summary of adverse reactions

*Gastrointestinal disorders* (Frequent): Dry mouth<sup>8</sup>, weight loss, diarrhoea, vomiting, decreased appetite and abdominal pain or discomfort.<sup>7</sup>

*Nervous system disorders* (Frequent): Somnolence, sedation, psychomotor slowing, lethargy, dizziness and fatigue.<sup>7</sup>

*Investigations* (Frequency unknown): Elevated liver transaminases.<sup>7</sup>

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

### 4.8 d Paediatric Population

**CANNISOL DAILY CAPSULES** is not recommended for use in children or adolescents below 18 years of age.

### 4.8 e Other special populations

No clinical data are available on the effects of **CANNISOL DAILY CAPSULES** on other special populations.

## 4.9 Overdose

No known side effects were reported for overdosage of oral CBD. CBD<sup>7,14</sup> overdose is symptomatic and supportive.

Side effects listed in section 4.8 can be precipitated and/or be of increased severity.

### Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare 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>.

## 5. PHARMACOLOGICAL PROPERTIES:

### 5.1 Pharmacodynamic properties

D 34.13 Other. Complementary Medicine. Health Supplement.

#### *Mechanism of action:*

CBD can interact or alter the endocannabinoid signalling pathways (via the cannabinoid receptors)<sup>15</sup> and the non-endocannabinoid pathways (interactions with serotonin 5-HT<sub>1A</sub> receptors, GPR55 receptors and vanilloid-1 receptors).<sup>16</sup> CBD also inhibits the degradation of the endocannabinoid, anandamide, which may contribute to its antipsychotic properties.<sup>16</sup>

#### *Pharmacodynamic effects:*

According to pre-clinical studies, CBD has anti-inflammatory, analgesic, antiemetic, antipsychotic, anti-ischemic, anxiolytic, and antiepileptiform effects.<sup>6</sup>

### 5.2 Pharmacokinetic properties

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

*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.<sup>17</sup> CBD and its metabolites are more than 94 % protein bound.<sup>8</sup>

*Metabolism:* CBD is vastly metabolized in the liver.<sup>17</sup> It undergoes hydroxylation, oxidation, beta-oxidation, conjugation, and epoxidation.<sup>8</sup>

*Excretion:* The half-life of CBD is between 56 to 61 hours.<sup>7</sup> CBD is excreted in the faeces, with minor renal clearance.<sup>7</sup>

### 5.3 Preclinical safety data

When used orally and appropriately in adults, CBD is recognized as possibly safe.<sup>8</sup>

## 6. PHARMACEUTICAL PARTICULARS:

### 6.1 List of excipients

- Alpha tocopheryl acetate (Vitamin E)
- Colloidal silicon dioxide
- *Glycine max* (L.) Merr. (Lecithin/soybean) oil
- Magnesium stearate (vegetable grade)
- Medium chain triglyceride (MCT) oil

- Microcrystalline cellulose

#### **6.2 Incompatibilities**

In the absence of compatibility studies, **CANNISOL DAILY 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**

60's: White vegetable capsules are available in a 175 mL white PET container, sealed with a white screw cap and an induction seal. Container is placed in a unit carton together with a leaflet.

#### **6.6 Special precautions for disposal**

Return all unused **CANNISOL DAILY CAPSULES** to the pharmacist. Do not dispose of unused **CANNISOL DAILY CAPSULES** in drains or sewerage systems (e.g. toilets).

### **7. HOLDER OF CERTIFICATE OF REGISTRATION**

Progress Biolabs (Pty) Ltd  
183 Albion Springs  
Rondebosch  
Western Cape  
7708  
South Africa  
Email: [customercare@cannisol.co.za](mailto:customercare@cannisol.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 2022

**PATIENT INFORMATION LEAFLET**  
**CANNISOL DAILY CAPSULES**

**SCHEDULING STATUS:** [S0]

**CANNISOL DAILY CAPSULES 10 mg** (capsules)

Cannabidiol

Sugar free

Contains allergen: Soy lecithin

**D 34.13 Other. Complementary Medicine. Health Supplement.**

Health supplements are intended only to complement health or supplement the diet.

**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. CANNISOL DAILY CAPSULES** is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **CANNISOL DAILY CAPSULES** carefully to get the best results from it.

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

**1. What CANNISOL DAILY CAPSULES is and what is it used for**

**CANNISOL DAILY CAPSULES** is made from pure, high quality ingredients and contains Cannabidiol (CBD). It may help the body's natural responses to anxiousness,<sup>1,2</sup> pain and inflammation.<sup>3-6</sup> **CANNISOL DAILY CAPSULES** is indicated for adults 18 years and older.

**2. What you need to know before you take CANNISOL DAILY CAPSULES**

**Do not take CANNISOL DAILY CAPSULES:**

- If you are hypersensitive (allergic) to cannabidiol<sup>7</sup>, or to any of the other ingredients in **CANNISOL DAILY CAPSULES** (listed in section 6).
- Not recommended in women of childbearing age, those planning pregnancy, and those who are pregnant, or breastfeeding.<sup>6,8</sup>

**Warnings and precautions**

- Use with caution if you have mild or severe liver disease.<sup>7</sup>
- Use with caution in patients with Parkinson disease.<sup>8</sup>
- Patients who have or had mood problems or depression should be monitored.<sup>7</sup>
- CBD may cause delayed reactions, sedation and drowsiness.<sup>7</sup>
- Contains allergens: Soy lecithin
- Avoid use in children or adolescents below 18 years of age.

**Children and adolescents**

**CANNISOL DAILY CAPSULES** is not recommended for use in children or adolescents below 18 years of age.

**Other medicines and CANNISOL DAILY 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 **CANNISOL DAILY CAPSULES** in combination with medicines or treatments such as:

- Pain medication, such as methadone, as the concomitant use may theoretically increase methadone levels, causing additive adverse effects.<sup>8</sup>
- Antiepileptic or anticonvulsant medication (such as brivaracetam, eslicarbazepine, rufinamide, stiripentol, topiramate, valproate, carbamazepine, and zonisamide), as the concomitant use may result in liver damage due to elevated liver enzymes.<sup>7</sup>
- Blood thinners, as CBD may elevate warfarin levels, consequently increasing the risk of bleeding.<sup>8</sup> In addition, increased valproate may also result in increased bleeding due to low blood platelet count.<sup>8</sup>
- Anti-estrogens (Estrogen blockers), as the chronic use of CBD may theoretically reduce tamoxifen's active metabolites.<sup>8</sup>
- Antimanic agents (Mood stabilizers), as CBD may theoretically cause lithium toxicity when using concomitantly.<sup>8</sup>
- Birth control medication, as the concomitant use with high dosages of CBD is speculated to interfere with contraceptives. If a female patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.<sup>9-12</sup>
- Caffeine, as CBD may increase caffeine levels when using concomitantly.<sup>8</sup>
- Central nervous system (CNS) depressants (zopiclone, diazepam, alprazolam, clobazam etc.) as it may increase the risk of sedation and drowsiness.<sup>6,8</sup> 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.<sup>8</sup>
- Glucuronidated agents, as CBD may increase the level of certain glucuronidated agents when using concomitantly.<sup>8</sup>
- Immunosuppressants (such as tacrolimus and sirolimus) as concomitant use may result in elevated immunosuppressant plasma levels and consequently additive side effects.<sup>8</sup>
- Kinase inhibitor, everolimus, as co-administration may cause additive adverse effects.<sup>8</sup>
- Antiretroviral medication like protease inhibitors, 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.<sup>7</sup>
- Phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin, as it will decrease CBD plasma concentrations, which may lower the efficacy of CBD-containing products.<sup>7</sup>

#### **Interactions with diseases/impairments**

*Liver impairment:* CBD may cause an increase in liver enzymes if you have moderate or severe liver impairment.<sup>7</sup>

*Parkinson disease:* CBD may worsen symptoms associated with Parkinson disease.<sup>8</sup>

#### **CANNISOL DAILY CAPSULES with food and drink**

Do not take **CANNISOL DAILY CAPSULES** with alcohol as it may increase the risk of sedation and drowsiness.<sup>7</sup>

Take **CANNISOL DAILY CAPSULES** with a meal high in fat for optimal CBD absorption and bioavailability.<sup>13</sup>

CBD may increase caffeine levels.<sup>8</sup>

#### **Pregnancy and breastfeeding**

Not recommended for use during pregnancy and lactation.<sup>6,8</sup>

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 of **CANNISOL DAILY CAPSULES** may interfere with the daily activities of a patient. It is possible that **CANNISOL DAILY CAPSULES** would affect the ability to drive or operate machinery, as CBD may cause delayed reactions, drowsiness and sedation.<sup>7</sup> Patients should ensure that they do not engage in the above activities until they are aware of the measure to which of **CANNISOL DAILY CAPSULES** affects them.

### **3. How to take CANNISOL DAILY CAPSULES**

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

Always take **CANNISOL DAILY 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+)

Take **CANNISOL DAILY CAPSULES** orally.

Take 1-2 capsules daily, preferably with a meal or as directed by your healthcare practitioner.

DO NOT EXCEED THE DAILY RECOMMENDED DOSAGE OF 20 MG CBD.

#### If you take more **CANNISOL DAILY CAPSULES** than you should

No known side effects were reported for overdosage of oral CBD. CBD<sup>7,14</sup> overdose is symptomatic and supportive.

Side effects listed in section 4 can be precipitated and/or be of increased severity.

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 **CANNISOL DAILY CAPSULES**

Always take **CANNISOL DAILY 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

**CANNISOL DAILY CAPSULES** can have side effects.

Not all side effects reported for **CANNISOL DAILY CAPSULES** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CANNISOL DAILY CAPSULES**, please consult your healthcare provider for advice.

##### Side effects associated with CBD:

###### Frequent:

- Dry mouth<sup>8</sup>, diarrhoea, vomiting, decreased appetite, weight loss and abdominal pain or discomfort.<sup>7</sup>
- Drowsiness, sedation, delayed reactions, lethargy, dizziness and fatigue.<sup>7</sup>

###### Frequency unknown:

- Elevated liver enzymes (transaminases).<sup>7</sup>

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 **CANNISOL DAILY CAPSULES**.

#### 5. How to store **CANNISOL DAILY 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 **CANNISOL DAILY CAPSULES** to your pharmacist. Do not dispose of unused **CANNISOL DAILY CAPSULES** in drains or sewerage systems (e.g. toilets).

#### 6. Contents of the pack and other information

##### What **CANNISOL DAILY CAPSULES** contains:

Active ingredient per capsule is 10 mg *Cannabis sativa* L. cannabidiol (CBD) isolate.

The other ingredients are: α-Tocopheryl acetate (Vitamin E), colloidal silicon dioxide, *Glycine max* L. Merr. (Lecithin/soybean) oil, magnesium stearate (vegetable grade), medium chain triglyceride (MCT) oil and microcrystalline cellulose.

Contains allergen: Soy lecithin

##### What **CANNISOL DAILY CAPSULES** looks like and contents of the pack

60’s: White vegetable capsules are available in a 175 mL white PET container, sealed with a white screw cap and an

induction seal. Container is placed in a unit carton together with a leaflet.

**Holder of Certificate of Registration and Manufacturer**

Progress Biolabs (Pty) Ltd  
183 Albion Springs  
Rondebosch  
Western Cape  
7708  
South Africa  
Email: [customercare@cannisol.co.za](mailto:customercare@cannisol.co.za)

**This leaflet was last revised in**

July 2022





# PASIËNTINLIGTINGSBLAD

## CANNISOL DAILY CAPSULES

SKEDULERINGSSTATUS: [S0]

CANNISOL DAILY CAPSULES 10 mg (kapsules)

Kannabidiol

Suikervry

Bevat allergeen: Soja lesitien

### D 34.13. Ander. Komplementêre Medisyne. Gesondheidsaanvulling.

Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

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. CANNISOL DAILY CAPSULES is beskikbaar sonder 'n dokter se voorskrif om u gesondheid te ondersteun. U moet egter steeds CANNISOL DAILY CAPSULES versigtig gebruik om die beste resultate daarmee te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie CANNISOL DAILY 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 voubiljet

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

### 1. Wat CANNISOL DAILY CAPSULES is en waarvoor dit gebruik word

CANNISOL DAILY CAPSULES is gemaak van hoë gehalte suiwer betanddele en bevat Kannabidiol (CBD). Dit kan help met die die liggaam se natuurlike reaksies teen angstigheid, pyn en inflammasie.

CANNISOL DAILY CAPSULES is aangedui vir volwassenes 18 jaar en ouer.

### 2. Wat u moet weet voordat u CANNISOL DAILY CAPSULES neem

Moet nie CANNISOL DAILY CAPSULES neem nie:

- Indien u hipersensitief (allergies) is vir kannabidiol, of vir enige van die ander bestanddele in CANNISOL DAILY CAPSULES (gelys in afdeling 6).
- Nie aanbeveel vir vroue van vrugbare ouderdom, diegene wat swangerskap beplan, wat swanger is, of borsvoed nie.

### Waarskuwings en voorsorgmaatreëls

- Gebruik versigtig indien u ligte tot ernstige lewer probleme het.
- Gebruik versigtig indien u Parkinson-siekte het.
- Pasiënte wat gemoedsprobleme of depressie het of gehad het, moet gemonitor word.
- CBD mag sedasie, vertraagde reaksies en lomerigheid veroorsaak.
- Bevat allergeen: Soja lesitien
- Vermoed gebruik in kinders of adolessente jonger as 18 jaar.

### Kinders en adolessente

CANNISOL DAILY CAPSULES word nie vir kinders of adolessente jonger as 18 jaar aanbeveel nie.

## Ander medikasie en CANNISOL DAILY CAPSULES

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

Raadpleeg u dokter as u **CANNISOL DAILY CAPSULES** in kombinasie met die volgende medisyne wil gebruik:

- Pynmedikasie, soos metadoon, omrede die gesamentlike gebruik teoreties addisionele nadelige gevolge kan hê.
- Anti-epileptiese medikasie (soos brivaracetam, eslikarbapiesien, rufinamied, stiripentol, topiramaat, valproaat, karbamasesien en zonisamied), omrede die kombinasie kan lei tot lewerskade weens verhoogde transaminase ensiemvlakke in die lewer.
- Bloedverduiners, omrede CBD warfarienvlakke kan verhoog, wat gevolglik die risiko van bloeding kan verhoog. Boonop kan valproaat ook lei tot 'n verlaagde bloedplaatjie telling. Boonop kan verhoogde valproaatvlakke ook verhoogde bloeding tot gevolg hê weens 'n verlaagde bloedplaatjietelling.
- Anti-oestrogene (Estrogeen blokkeerders), omrede die chroniese gebruik van CBD teoreties tamoksifen se aktiewe metaboliete kan verminder.
- Antimaniese middels (Gemoedsstabiliseerders), omrede CBD teoreties litiumtoksisiteit kan veroorsaak wanneer dit gelyktydig gebruik word.
- Voorbehoedmiddels, omrede die gesamentlike gebruik teoreties deurbraakbloeding kan verhoog en die effektiwiteit van voorbehoedmiddels kan verminder, wat gevolglik kan lei tot 'n verhoogde risiko vir ongewenste swangerskap.
- Kafeïen, omrede CBD kafeïenvlakke kan verhoog wanneer dit gelyktydig gebruik word.
- Sentrale senuweestelsel (SSS) depressante (bv. zopikloon, diasepien, alprazolam, klobazam ens.), omdat die gesamentlike gebruik met CBD die risiko van sedasie en lomerigheid kan verhoog. Kruie/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.
- Geglukuronideerde middels, omrede CBD die vlak van sekere glukuronideerde middels kan verhoog wanneer dit gelyktydig 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 soos protease inhibitore, antibiotika soos eritromisien en klaritromisien, antidepressante soos fluvoksamien, en proton pomp inhibeerders (PPI's) soos omeprasool, aangesien hierdie middels die plasmavlakke van CBD kan verhoog en sodoende die nuwe-effekte daarvan vererger.
- Fenobarbital, fenitoïen, karbamasesien, prednison en rifampisien, omrede dit CBD plasmavlakke verlaag en gevolglik ook die effektiwiteit van CBD verminder.

## Interaksies met siektes

*Lewerprobleme:* CBD kan 'n toename in lewerensiemte veroorsaak indien u matige of ernstige lewerprobleme het.

*Parkinson-siekte:* CBD kan simptome wat met Parkinson-siekte geassosieer word, vererger.

## CANNISOL DAILY CAPSULES met kos en drinkgoed

Die gesamentlike inname van alkohol en **CANNISOL DAILY CAPSULES** mag sedasie en lomerigheid veroorsaak.

Neem **CANNISOL DAILY CAPSULES** met 'n maaltyd hoog in vet vir optimale CBD opname en biobeskikbaarheid.

CBD kan kafeïenvlakke verhoog.

## 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

Dit is nie altyd moontlik om te voorspel tot watter mate **CANNISOL DAILY CAPSULES** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Dit is moontlik dat **CANNISOL DAILY 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 **CANNISOL DAILY CAPSULES** hulle beïnvloed nie.

## 3. Hoe om CANNISOL DAILY CAPSULES te neem

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

Neem **CANNISOL DAILY CAPSULES** soos voorgeskryf in hierdie voubiljet 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+)**

Neem **CANNISOL DAILY CAPSULES** oraal.

Neem 1-2 kapsules daaglik, verkieslik saam met 'n maaltyd of soos aanbeveel deur u gesondheidsorgpraktisyn.

MOET NIE DIE AANBEVELE DAAGLIKSE DOSIS VAN 20 MG CBD OORSKRY NIE.

#### **Indien u meer CANNISOL DAILY CAPSULES geneem het as wat u moes**

Geen bekende nuwe-effekte is aangemeld vir oordosering van orale CBD nie. CBD oordosering is simptome en ondersteunend. Die nuwe-effekte wat in afdeling 4 gelys word, kan ontstaan en/of die graad daarvan kan toeneem.

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

#### **Indien u vergeet om CANNISOL DAILY CAPSULES te neem**

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

#### **4. Moontlike nuwe-effekte**

**CANNISOL DAILY CAPSULES** kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir **CANNISOL DAILY CAPSULES** is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van **CANNISOL DAILY CAPSULES**, raadpleeg u gesondheidsorgwerker vir advies.

#### **Neue-effekte geassosieer met CBD:**

##### Algemeen

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

##### Frekwensie onbekend

- Verhoogde lewerensieme (transaminases).

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 voubiljet gelys is nie. U kan ook nuwe-effekte by 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 **CANNISOL DAILY CAPSULES** te verskaf.

#### **5. Hoe om CANNISOL DAILY 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 **CANNISOL DAILY CAPSULES** na u apteker terug. Moenie ongebruikte **CANNISOL DAILY CAPSULES** in afvoerpype of rioolsisteme (byvoorbeeld toilette) weggooi nie.

#### **6. Inhoud van die verpakking en ander inligting**

##### **Wat CANNISOL DAILY CAPSULES bevat:**

Aktiewe bestanddeel per kapsule is 10 mg *Cannabis sativa* L. kannabidiol (CBD) isolaat.

Die ander bestanddele is:  $\alpha$ -Tokoferielasetaat (Vitamien E), *Glycine max* L. Merr. (Lesitien/sojaboon) olie, kolloïdale silikondioksied, magnesiumstearaat (plantaardige afkoms), medium ketting trigliseried (MKT) olie en mikrokristallyne sellulose.

Bevat allergeen: Soja lesitien

**Hoe CANNISOL DAILY CAPSULES lyk en die inhoud van die verpakking**

60's: Wit plant-gebaseerde kapsules beskikbaar in 'n 175 ml wit PET houer wat geseël word met 'n wit skroef dop en 'n induksie seël. Die houer is tesame met 'n pamflet in 'n eenheidskarton.

**Houer van die Sertifikaat van Registrasie en Vervaardiger**

Progress Biolabs (Pty) Ltd

183 Albion Springs

Rondebosch

Wes-Kaap

7708

Suid-Afrika

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**Hierdie voubiljet was laaste hersien in**

Julie 2022

PBCAN001-PIFIL.003

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