

PROFESSIONAL INFORMATION

Cannisol™ DAILY CAPSULES

SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM:

Cannisol™ DAILY CAPSULES (10 mg) (capsules).

COMPOSITION:

Active ingredient per capsule:

Cannisol™ DAILY CAPSULES (10 mg): 10,0 mg *Cannabis sativa* L. cannabidiol (CBD isolate)

Inactive ingredients: Alpha tocopheryl acetate (vitamin E), colloidal silicon dioxide, *Glycine max* L. Merr. (lecithin/soybean) oil, magnesium stearate, medium chain triglyceride (MCT) oil and microcrystalline cellulose.

Free from: Artificial colours, flavours, sweeteners, starch, milk, lactose, gluten, wheat, yeast and porcine.

Contains allergens: Soybean

CATEGORY AND CLASS:

Category of medicine: D

Class: 34.6 Fats, Oils and Fatty Acids

Complementary Medicine. Health supplement.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Cannabidiol (CBD) is a cannabinoid. Unlike Tetrahydrocannabinol (THC), CBD does not cause euphoria or intoxication.

***Cannabis sativa* L. cannabidiol (CBD):** Pre-clinical studies suggest that CBD has anti-ischemic, anti-epileptiform, anti-inflammatory, anti-psychotic, anti-emetic, anxiolytic and analgesic effects.

Pharmacokinetic properties:

The active ingredient in this formulation is well known. CBD taken by an oral route takes between 2,5 and 5 hours to reach maximal concentration in the blood. The half-life is between 56 to 61 hours. Pharmacokinetic studies have not been performed on **Cannisol™ DAILY CAPSULES**.

INDICATIONS:

Cannisol™ DAILY CAPSULES helps your body's natural responses to anxiousness, pain and inflammation.

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients (see "COMPOSITION").
- Not recommended during pregnancy and/or lactation, as no studies have been conducted in this population group (see "PREGNANCY and LACTATION").
- Not to be given to children

WARNINGS and SPECIAL PRECAUTIONS:

There are no known warnings or special precautions for **Cannisol™ DAILY CAPSULES**.

The use of CBD in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes.

Patients who have or had mood problems or depression should be monitored.

CBD may cause psychomotor slowing, sedation and somnolence (see "INTERACTIONS" and "SIDE EFFECTS").

Effects on the ability to drive and use machinery:

No studies have been performed regarding the effect of **Cannisol™ DAILY CAPSULES** on the ability to drive or operate machinery. It is possible that **Cannisol™ DAILY CAPSULES** would affect the ability to drive or operate machinery, as it may cause psychomotor slowing, somnolence and sedation. Please exercise care until you are certain that your ability to perform such activities is not affected.

INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **Cannisol™ DAILY CAPSULES** and other medication and/or food.

CBD might interact with the following medicines, herbs or supplements:

Concomitant use of CBD with central nervous system (CNS) depressants (such as benzodiazepines and barbiturates) or alcohol may increase the risk of somnolence and sedation.

Co-administration of CBD with antiepileptic medication may increase antiepileptic plasma levels and elevate liver transaminases.

Concomitant use of CBD and moderate or strong inhibitors of CYP3A4 or CYP2C19 may increase CBD plasma concentrations, which may result in a greater risk of side effects. Inhibitors include protease inhibitors like antiretroviral medication, proton pump inhibitors like omeprazole, selective serotonin reuptake inhibitors (SSRI's) like fluoxetine and fluvoxamine and antibiotics like clarithromycin and erythromycin.

Alternatively, the co-administration of CBD with strong inducers of CYP3A4 or CYP2C19 may decrease CBD plasma levels, which may lower the efficacy of CBD-containing products. This includes carbamazepine, phenytoin, phenobarbital, primidone and rifampicin.

HUMAN REPRODUCTION:**Pregnancy and lactation:**

Not recommended for use during pregnancy or whilst breastfeeding, as the safety and efficacy of **Cannisol™ DAILY CAPSULES** has not been established for this population group.

DOSAGE AND DIRECTIONS FOR USE:**Adults (18 years and older)**

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

Do not take more than two capsules per day.

Do not exceed the recommended maximum daily dose of 20 mg CBD.

SIDE EFFECTS:

There are no known side effects with **Cannisol™ DAILY CAPSULES**.

Side effects associated with CBD:**Gastrointestinal disorders:**

Frequency: Abdominal pain or discomfort, dry mouth, diarrhoea, decreased appetite, vomiting and weight loss.

Investigations:

Frequency unknown: Elevated liver transaminases.

Nervous system disorders:

Frequency: Sedation, somnolence, dizziness, psychomotor slowing, lethargy and fatigue.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No known side effects were reported for overdosage of CBD.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION of Cannisol™ DAILY CAPSULES:

White, size 0 vegetable capsules.

PRESENTATION of Cannisol™ DAILY CAPSULES:

60's: White vegetable capsules are available in a 175 ml white PET container, sealed with a white screw cap and an induction seal.

STORAGE INSTRUCTIONS:

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place at or below 25 °C.

Avoid excessive heat.

Tamper resistant. Do not use if seal under cap is broken.

Do not use after expiry date stated on the label.

REGISTRATION NUMBER:

To be allocated.

Cannisol™ DAILY CAPSULES is an unregistered medicine and has not been evaluated by SAHPRA for its quality, safety or intended use.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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



DATE OF PUBLICATION: April 2020

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PATIENT INFORMATION LEAFLET

This leaflet tells you about **Cannisol™ DAILY CAPSULES**

Complementary Medicine. Health Supplement.

SCHEDULING STATUS: [S0]

PROPRIETARY NAME AND DOSAGE FORM:

Cannisol™ DAILY CAPSULES (10 mg) (capsules).

Read all of this leaflet carefully because it contains important information for you. **Cannisol™ DAILY CAPSULES** is available without a doctor's prescription. 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 pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve

WHAT Cannisol™ DAILY CAPSULES CONTAINS:

Active ingredient per capsule:

Cannisol™ DAILY CAPSULES (10 mg):

10,0 mg *Cannabis sativa* L. cannabidiol (CBD isolate)

Inactive ingredients: Alpha tocopheryl acetate (vitamin E), colloidal silicon dioxide, *Glycine max* L. Merr. (lecithin/soybean) oil, magnesium stearate, medium chain triglyceride (MCT) oil and microcrystalline cellulose.

Free from: Artificial colours, flavours, sweeteners, starch, milk, lactose, gluten, wheat, yeast and porcine.

Contains allergens: Soybean

WHAT Cannisol™ DAILY CAPSULES IS USED FOR:

Cannisol™ DAILY CAPSULES helps your body's natural responses to anxiousness, pain and inflammation.

BEFORE YOU TAKE Cannisol™ DAILY CAPSULES:

Do NOT take Cannisol™ DAILY CAPSULES:

- If you are allergic to any of the ingredients (see "WHAT **Cannisol™ DAILY CAPSULES** CONTAINS").
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").
- Not to be given to children.

Take special care with Cannisol™ DAILY CAPSULES:

Use with caution if you have mild or severe hepatic impairment (liver disease).

CBD may cause delayed reactions, sedation and somnolence.

Cannisol™ DAILY CAPSULES does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

Please consult your doctor or pharmacist prior to use if you:

- Have mild or severe hepatic impairment (liver disease).
- Have or had mood problems or depression.

Taking Cannisol™ DAILY CAPSULES with food and drink:

There are no known side effects to taking **Cannisol™ DAILY CAPSULES** with food and drink. However, consuming alcohol in combination with CBD may increase the risk of sedation and drowsiness.

Pregnancy and breastfeeding:

Do not use **Cannisol™ DAILY CAPSULES** during pregnancy or while you are breastfeeding your baby, as safety and efficacy have not been established.

Driving and using machinery:

No studies have been performed on the effect of **Cannisol™ DAILY CAPSULES** on the ability to drive or use machinery. 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. Please exercise care until you are certain that your ability to perform such activities is not affected.

Taking other medicines with Cannisol™ DAILY CAPSULES:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **Cannisol™ DAILY CAPSULES** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Consult your doctor if you want to take **Cannisol™ DAILY CAPSULES** in combination with medicines or treatments such as:

- Central nervous system (CNS) depressants (e.g. alprazolam, diazepam, zopiclone, etc.) as it may increase the risk of sedation.
- Antiepileptic or anticonvulsant medication as concomitant use may result in elevated liver enzymes and consequently liver damage.
- Protease inhibitors like antiretroviral medication, proton pump inhibitors like omeprazole, antidepressants like fluoxetine and fluvoxamine and antibiotics like clarithromycin and erythromycin, since these might increase CBD plasma concentrations leading to a greater risk of side effects.
- Carbamazepine, phenytoin, phenobarbital, primidone and rifampicin as it may decrease CBD plasma concentrations, which in turn may lower the efficacy of CBD-containing products.

HOW TO TAKE Cannisol™ DAILY CAPSULES:

Always take **Cannisol™ DAILY CAPSULES** as your doctor has instructed you. You should verify with your doctor or pharmacist if you are unsure.

Adults (18 years and older)

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

Do not take more than two capsules per day.

Do not exceed the recommended maximum daily dose of 20 mg CBD.

If the symptoms worsen or persist, please consult your healthcare practitioner.

If you take more Cannisol™ DAILY CAPSULES than you should:

No known information.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, immediately seek help at 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 (see "HOW TO TAKE **Cannisol™ DAILY CAPSULES**"). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

There are no known side effects associated with **Cannisol™ DAILY CAPSULES**.

Not all side effects reported for the ingredients are included in this leaflet. Should your general health worsen while taking **Cannisol™ DAILY CAPSULES**, please consult your doctor, pharmacist or other healthcare professional for advice.

Side effects associated with CBD:

- Abdominal pain or discomfort, dry mouth, diarrhoea, decreased appetite, vomiting and weight loss (*Frequent*).
- Elevated liver enzymes (transaminases) (*Frequency unknown*).
- Sedation, somnolence, dizziness, psychomotor slowing, lethargy and fatigue (*Frequent*).

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

STORAGE AND DISPOSING OF Cannisol™ DAILY CAPSULES

KEEP OUT OF REACH OF CHILDREN.

Store in a cool, dry place at or below 25 °C.

Avoid excessive heat.

Tamper resistant. Do not use if seal under cap is broken.

Do not use after expiry date stated on the label.

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).

IDENTIFICATION of Cannisol™ DAILY CAPSULES:

White size 0 vegetable capsules.

PRESENTATION of Cannisol™ DAILY CAPSULES:

60's: White vegetable capsules are available in a 175 ml white PET container, sealed with a white screw cap and an induction seal.

REGISTRATION NUMBER:

To be allocated.

Cannisol™ DAILY CAPSULES is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

Progress Biolabs (Pty) Ltd
183 Albion Springs
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7708
South Africa
Email: customercare@cannisol.co.za



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PASIËNTINLIGTINGSBLAD

Inligting oor **Cannisol™ DAILY CAPSULES**

Komplementêre Medisyne. Gesondheidsaanvulling.

SKEDULERINGSSTATUS: [S0]

EIENDOMSNAAM EN DOSEERVORM:

Cannisol™ DAILY CAPSULES (10 mg) (kapsules).

Lees die hele inligtingsblad deeglik, want dit bevat belangrike inligting. **Cannisol™ DAILY CAPSULES** is beskikbaar sonder 'n dokter se voorskrif. 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 apteker.
U moet 'n dokter raadpleeg indien u simptome vererger.

WAT Cannisol™ DAILY CAPSULES BEVAT:

Aktiewe bestanddeel per kapsule:

Cannisol™ DAILY CAPSULES (10 mg):

10,0 mg *Cannabis sativa* L. cannabidiol (CBD isolaat)

Onaktiewe bestanddele: Alfa tokoferiel asetaat (vitamien E), kolloïdale silikondioksied, *Glycine max* L. Merr. (lesitien/sojaboon) oile, magnesiumstearaat, medium ketting trigliseried (MKT) oile en mikrokristallyne sellulose.

Vry van: Kunsmatige kleure, geure, versoeters, stysel, melk, laktose, gluten, koring, gis en vark.

Bevat allergene: Sojaboon

WAARVOOR Cannisol™ DAILY CAPSULES GEBRUIK WORD:

Cannisol™ DAILY CAPSULES help jou liggaam se natuurlike reaksies teen angstigheid, pyn en inflammasie.

VOOR U Cannisol™ DAILY CAPSULES NEEM:

Moet nie Cannisol™ DAILY CAPSULES neem nie:

- Indien u allergies is vir enige van die bestanddele (sien "WAT **Cannisol™ DAILY CAPSULES** BEVAT").
- Indien u swanger is of u baba borsvoed (sien "Swangerskap en borsvoeding").

Neem spesiale sorg met Cannisol™ DAILY CAPSULES:

Gebruik versigtig indien u 'n geskiedenis van lewer probleme het.

CBD mag sedasie, vertraagde reaksies en lomerigheid veroorsaak.

Cannisol™ DAILY CAPSULES beoog nie om enige ongesteldheid of siektetoestand te genees nie en moet nie enige medikasie vervang nie. Mense wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg voor hulle hierdie produk gebruik.

Raadpleeg asseblief u dokter of apteker voor gebruik indien u:

- Ligte tot ernstige lewer probleme het.
- In die verlede of tans gemoedstoestand verstourings ondervind of aan depressie ly.

Cannisol™ DAILY CAPSULES met kos en drinkgoed:

Daar is geen bekende nuwe-effekte indien **Cannisol™ DAILY CAPSULES** saam met kos en drinkgoed geneem word nie.

Alhoewel, die gesamentlike inname van alkohol en CBD mag sedasie en lomerigheid veroorsaak.

Swangerskap en borsvoeding:

Moenie **Cannisol™ DAILY CAPSULES** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid hiervan nie bepaal is nie.

Bestuur en die gebruik van masjinerie:

Geen navorsingstudies is uitgevoer op **Cannisol™ DAILY CAPSULES** oor die effek op die vermoë om masjinerie te bestuur of te hanteer 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. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie beïnvloed nie.

Die neem van ander medisyne saam met Cannisol™ DAILY CAPSULES:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **Cannisol™ DAILY CAPSULES** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

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

- Sentrale senuweestelsel (SSS) depressante (bv. alprazolam, diasepien, zopikloon, ens.), omrede die gesamentlike gebruik die risiko van sedasie kan verhoog.
- Anti-epileptiese medikasie aangesien die kombinasie kan lei tot verhoogde transaminase ensiem vlakke en gevolglik lewerskade.
- Protease inhibitore soos anti-retrovirale middels, proton pomp inhibeerders soos omeprasool, antidepressante soos fluoksetien en fluvoksamien en antibiotika soos klaritromisien en eritromisien, aangesien dit plasma vlakke van CBD kan verhoog en sodoende die newe-effekte daarvan vererger.
- Karbamasepien, fenitoin, fenobarbital, primidoon en rifampisien, omrede dit CBD plasma vlakke verlaag en gevolglik die effek van CBD verminder.

HOE OM Cannisol™ DAILY CAPSULES TE GEBRUIK:

Neem **Cannisol™ DAILY CAPSULES** soos u dokter of mediese praktisyn dit aanbeveel. Maak asseblief seker by u dokter of apteker wat die aanbevole dosis is indien u onseker is.

Volwassenes (18 jaar en ouer)

Neem 1-2 kapsules per dag of soos aanbeveel deur u gesondheidsorgwerker.

Moet nie meer as twee kapsules per dag neem nie.

Moet nie 20 mg CBD per dag oorskry nie.

As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

Indien u meer Cannisol™ DAILY CAPSULES geneem het as wat u moes:

Geen bekende informasie.

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 sou gou as wat u onthou. Indien u egter nie van die vergete dosis onthou voordat dit tyd is vir die volgende dosis is nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM **Cannisol™ DAILY CAPSULES** TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

MOONTLIKE NEWE-EFFEKTE:

Daar is geen bekende newe-effekte wat gepaard gaan met **Cannisol™ DAILY CAPSULES** nie.

Nie alle newe-effekte van die bestanddele, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan terwyl u **Cannisol™ DAILY CAPSULES** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Neue-effekte wat gepaard gaan met CBD:

- Abdominale pyn en ongemak, droë mond, diarree, verlaagde eetlus, braking en gewigsverlies (*Algemeen*).
- Verhoogde lewerensieme (*Frekwensie onbekend*).
- Sedasie, lomerigheid, duisligheid, vertraagde reaksies, lusteloosheid en moegheid (*Algemeen*).

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

BERGING EN WEGDOEN VAN Cannisol™ DAILY CAPSULES:

HOU BUITE BEREIK VAN KINDERS.

Bewaar in 'n koel, droë plek by of benede 25 °C.

Vermy oormatige hitte.

Peutervry. Moenie gebruik as die seël onder die dop gebreek is nie.

Moenie gebruik na die vervaldatum op die etiket nie.

Neem alle ongebruikte **Cannisol™ DAILY CAPSULES** na u apteker terug. Moenie ongebruikte **Cannisol™ DAILY CAPSULES** in afvoerpype of rioolsisteme (byvoorbeeld toilette) weggooi nie.

IDENTIFIKASIE VAN Cannisol™ DAILY CAPSULES:

Wit, grootte 0 plant-gebaseerde kapsule.

AANBIEDING VAN Cannisol™ DAILY CAPSULES:

Cannisol™ DAILY CAPSULES (10 mg):

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.

REGISTRASIENOMMER:

Sal toegeken word.

Cannisol™ DAILY CAPSULES is nie geregistreer nie en nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

NAAM EN SAKEADRES VAN DIE HOUER VAN DIE REGISTRASIE:

Progress Biolabs (Pty) Ltd

183 Albion Springs

Rondebosch

Wes-Kaap

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Suid-Afrika

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