

**PATIENT INFORMATION LEAFLET****CANNAMICS 10 mg pastilles****SCHEDULING STATUS****S0****PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:****CANNAMICS 10 MG PASTILLES**

Hemp oil extract containing 10 mg CBD (cannabidiol) per pastille

Contains sweeteners (sugar alcohol, sorbitol 394 mg and maltitol 78 mg per pastille)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CANNAMICS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

**What is in this leaflet**

1. What CANNAMICS is and what it is used for
2. What you need to know before you take CANNAMICS
3. How to take CANNAMICS
4. Possible side effects
5. How to store CANNAMICS
6. Contents of the pack and other information

**1. What CANNAMICS contains and what it is used for**

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CANNAMICS contains hemp oil/CBD (cannabidiol) intended to

- support everyday health and wellbeing

**2. What you need to know before you take CANNAMICS****Do not take CANNAMICS**

- if you are hypersensitive (allergic) to hemp oil/CBD (cannabidiol) or any of the other ingredients of CANNAMICS (listed in section 6)
- if you are pregnant and breastfeeding your baby
- if you are taking any medicine as stated under the subheading “**Other medicines and CANNAMICS**”
- if you are a child or adolescent (under the age of 18 years)

**Warnings and precautions**

Take special care

- If you have a liver condition
- CANNAMICS is not confectionery pastille. Do not take more than the recommended daily dose.

**Children and adolescents**

Do not give CANNAMICS to children and adolescents below the age of 18 years.

**Other medicines and CANNAMICS**

Always tell your health care provider, pharmacist or doctor if you are taking any other medicine (this includes all complementary or traditional medicine), as taking CANNAMICS with other medicine may cause undesirable interactions.

- The following treatments may interfere with the effectiveness of CANNAMICS:

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- Seizures/epilepsy - clobazam, phenytoin, carbamazepine, phenobarbitone, topiramate, valproate, primidone, lamotrigine
- Fungal infections - ketoconazole, fluconazole
- Tuberculosis - rifampicin
- HIV - efavirenz
- Heart - amiodarone, verapamil, clopidogrel, propranolol, digoxin
- High cholesterol - rosuvastatin, simvastatin, lovastatin, ezetimibe
- Prevention of blood clots - warfarin, dipyridamole, dabigatran
- High blood pressure - losartan, valsartan, telmisartan, prazosin
- Gastric problems - loperamide (to treat diarrhoea), cimetidine and omeprazole (used to treat stomach ulcers/hyperacidity), aprepitant (used to treat nausea and vomiting)
- Cancer - cyclophosphamide, imatinib, enzalutamide, methotrexate, paclitaxel, mitoxantrone, regorafenib, sorafenib, irinotecan
- Muscular pain/discomfort - carisoprodol
- Pain/inflammation - celecoxib, paracetamol, naproxen, ibuprofen, hydromorphone
- Nervous system disorders - fluvoxamine, fluoxetine, diazepam, haloperidol, bupropion, St. John's Wort (herbal supplement)
- Asthma - montelukast
- Diabetes - rosiglitazone, pioglitazone, sulphonylureas (e.g. chlorpropamide, glibenclamide), tolbutamide, glyburide, canagliflozin, dapagliflozin
- Bladder infections - nitrofurantoin
- Infections – erythromycin, clarithromycin
- Prevention of organ rejection for kidney transplants – mycophenolate
- Anaesthesia before surgery (propofol)

**PATIENT INFORMATION LEAFLET****CANNAMICS 10 mg pastilles****Taking CANNAMICS with food and drink**

Can be taken with or without food. Not to be taken with alcohol.

**Pregnancy and breastfeeding**

The safety and efficacy in pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CANNAMICS.

**Driving and using machinery**

It is not always possible to predict to what extent CANNAMICS may interfere with your daily activities. Do not drive or operate machinery until you know how CANNAMICS affects you

**CANNAMICS contains sweeteners sorbitol 394 mg and maltitol 78 mg per pastille**

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take CANNAMICS.

CANNAMICS may have a mild laxative effect.

**3. How to take CANNAMICS**

Always take CANNAMICS exactly as instructed in this leaflet. You should check with your doctor or pharmacist if you are unsure.

The usual dose is 1-2 pastilles daily, to be dissolved in the mouth. Do not take more than the recommended daily dosage.

**PATIENT INFORMATION LEAFLET****CANNAMICS 10 mg pastilles****If you take more CANNAMICS than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Please refer to possible side effects in the event of taking more than you should.

**If you forget to take a dose of CANNAMICS**

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

**4. Possible side effects**

CANNAMICS can have side effects.

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

If any of the following happens, stop taking CANNAMICS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- **rash or itching**
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CANNAMICS. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- sleepiness/drowsiness, listlessness, lacking energy, feeling tired, inability to fall asleep

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or stay asleep

- decreased appetite, decreased weight, diarrhoea, stomach cramps, vomiting
- increased occurrence of infections
- abnormal walk
- laboratory test results indicated increased amount of liver enzymes

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 “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 CANNAMICS.

Additionally, please send a mail to [pharmacovigilance@pharmadynamics.co.za](mailto:pharmacovigilance@pharmadynamics.co.za)

**5. How to store CANNAMICS**

**Store all medicines out of reach of children.**

Store at or below 25 °C.

Store in the original package.

Do not use after the expiry date stated on the carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

**6. Contents of the pack and other information****What CANNAMICS contains**

The active substance is hemp oil extract containing 10 mg CBD (cannabidiol) per pastille

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The other ingredients are:

Arabic gum, bees wax, capsicum, citric acid, lime flavouring, maltitol, sorbitol

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