

PATIENT INFORMATION LEAFLET
CANNABIS SUPPOSITORIES 25 MG CBD

Please read this leaflet carefully before you start taking this borderline product

-This borderline product is available without prescription for treatment (relieve) of health problems for which you do not need physician's advice. However, Cannabis suppositories 25 mg CBD should be used carefully in order to be more useful.

-Keep this leaflet; you may need to read it again.

-Consult your physician or pharmacist if you have further questions.

This leaflet contains:

- 1. What is borderline product Cannabis suppositories 25 mg CBD and what is used for*
- 2. What you need to know before you take the borderline product Cannabis suppositories 25 mg CBD?*
- 3. How to take borderline product Cannabis suppositories 25 mg CBD*
- 4. Possible side effects*
- 5. Storage and shelf life of borderline product Cannabis suppositories 25 mg CBD*
- 6. More information*

1. What is borderline product Cannabis suppositories 25 mg CBD and what is used for

Cannabis suppositories 25 mg CBD contain CBD hemp oil that is oil extract from annual grassy plant cannabis or hemp plant. The oily extract is with proven absence of pesticides and herbicides in the product. The extraction is carried out at low temperature without the use of organic solvents which provides the highest quality of the oil extract.

CBD hemp oil contains cannabinoids, primarily CBD (Cannabidiol), CBN (Cannabinol), CBG (Cannabigerol) and their carboxyl compounds. Cannabinoids bind to the CB1 and CB2 receptors of the endocannabinoid system causing immunomodulating effect (improving the immune system).

CBD hemp oil may contain terpens, omega fatty acids (omega-3, omega-6, omega-9), flavonoids, phytosterols, amino acids, glycosides, vitamins (A, B1, B2, B6, C, D, E, F), pigments, alkanes, nitrogen compounds that are important in the construction of cells, metabolic processes, maintaining the function of many systems and complete improvement of the general health condition.

CBD hemp oil contains THC (9-delta tetrahydrocannabinol) in amount less than 0,2%.

CBD hemp oil can help the body in conditions with malignant diseases, multiplex sclerosis, HIV and epileptic syndromes in childhood.

CBD hemp oil is not a substitute for standard prescribed therapy and especially it is not a substitute for standard therapy of abovementioned diseases.

The positive effects from taking Cannabis suppositories 25 mg CBD are manifested in:

- Conditions of stress, anxiety, nervousness, depression, muscle spasms;
- It is used for nausea and vomiting, especially during chemo or radiation therapy in malignant diseases;
- Helps maintaining the balance of intestinal flora;
- Relieves pain conditions of various origins, due to its anti-inflammatory action.

It can be used for prevention of cardiovascular diseases: helps in regulation of blood pressure, improves heart function, has cardioprotective effect, can help in regulation of elevated concentrations of lipids and cholesterol levels in the blood and can help in regulation of elevated concentration of blood glucose.

Cannabis suppositories 25 mg CBD are recommended for individuals with swallowing difficulties or intolerance to Cannabis hemp oil taste (flavour).

2. Information that should be known before taking borderline product Cannabis suppositories 25 mg CBD

Do not take/use Cannabis suppositories 25 mg CBD if you:

- are hypersensitive to any ingredient of suppositories;
- are pregnant or breastfeeding;
- have taken alcohol or other illegal substances.

Take special care with borderline product Cannabis suppositories 25 mg CBD if

There are not known conditions, diseases or taking other medicines where *Cannabis suppositories 25 mg CBD* should be applied with care.

Pregnancy and breastfeeding

Do not use Cannabis suppositories 25 mg CBD if you are pregnant or breastfeeding.

Effects on psychophysical abilities

Cannabis suppositories 25 mg CBD do not have psychotropic effect and it is not expected to influence ability to drive, to use machines or to perform heavy and unsafe work. However, as a result of insufficient data, it is not recommended to perform these activities during use of Cannabis suppositories 25 mg CBD.

Important information about some ingredients of Cannabis suppositories 25 mg CBD

There are no data about intolerance of any of the ingredients of Cannabis suppositories 25 mg CBD.

Taking/using other medicinal products

There are not known effects of taking other medicinal products at the same time with Cannabis suppositories 25 mg CBD.

Cannabis suppositories 25 mg CBD should not be taken at the same time with alcohol or illegal substances.

3. Information on proper use of borderline product Cannabis suppositories 25 mg CBD

Cannabis suppositories 25 mg CBD are intended for rectal use only.

Cannabis suppositories 25 mg CBD are recommended when it is necessary to take a single dose of 25 mg CBD at once.

Cannabis suppositories 25 mg CBD are recommended for individuals with swallowing difficulties or intolerance to Cannabis hemp oil taste (flavour).

Adults

One Cannabis suppository 25 mg CBD should be inserted in rectum once or twice daily, preferably one in the morning and one in the evening.

A Use of Cannabis suppository 25 mg CBD twice daily (in the morning and in the evening) is individual and consultation with a physician is recommended.

By using Cannabis suppositories 25 mg CBD twice daily, a daily dose of 50 mg CBD is received.

After insertion of suppository, it is recommended to remain lying down for about 15-20 minutes.

Children up to 14 years

One Cannabis suppository 25 mg CBD suppository should be inserted in rectum once daily.

By using Cannabis suppositories 25 mg CBD once daily, a daily dose of 25 mg CBD is received.

After insertion of suppository, it is recommended to remain lying down for about 15-20 minutes.

The dose may be increased upon recommendation by physician.

4. Information about possible side effects of borderline product Cannabis suppositories 25 mg CBD

There are not known side effects of Cannabis suppositories 25 mg CBD.

In case of signs of hypersensitivity, use of Cannabis suppositories 25 mg CBD should be discontinued!

5. Information about storage and expiry date of borderline product Cannabis suppositories 25 mg CBD

KANOIL® 25 mg suppositories should be kept out of reach of children!

The expiry date of Cannabis suppositories 25 mg CBD is stated on the package.

KANOIL® 25 mg suppositories should not be used after the expiry date !

KANOIL® 25 mg suppositories should be stored at a temperature of 25°C in original package.

6. Additional information about borderline product Cannabis suppositories 25 mg CBD

What Cannabis suppositories 25 mg CBD contain?

One Cannabis suppository 25 mg CBD contains:

-25 mg CBD (Cannabidiol extracted from Cannabis plant)

-Hard fat

What Cannabis suppositories 25 mg CBD look like and package size

The box contains 5 suppositories (one PVC/PE blister x 5 suppositories) and patient information leaflet.

The box contains 10 suppositories (two PVC/PE blisters x 5 suppositories) and patient information leaflet.

Marketing Authorization Holder of Cannabis suppositories 25 mg CBD

REPLEK FARM Ltd. Skopje

Kozle street no.188, 1000 Skopje, R.N. Macedonia

Manufacturer of Cannabis suppositories 25 mg CBD

REPLEK FARM LTD Skopje

Kozle street no. 188, 1000 Skopje, R.N. Macedonia

Number and date of registration into the Register for borderline products

Cannabis suppositories 25 mg CBD x 5: 11-5638/2 from 15.08.2016

Cannabis suppositories 25 mg CBD x 10: 11-5638/3 from 15.08.2016