

PATIENT INFORMATION LEAFLET

Cannabis hemp oil 10% CBD / 10 ml (1000mg CBD/ 10 ml oil)

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 Hemp oil 10% 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 hemp oil 10% CBD and what is used for*
- 2. What you need to know before taking borderline product Cannabis hemp oil 10% CBD*
- 3. How to take borderline product Cannabis hemp oil 10% CBD*
- 4. Possible side effects*
- 5. Storage and shelf life of borderline product Cannabis hemp oil 10% CBD*
- 6. More information*

1.What is borderline product Cannabis hemp oil 10% CBD and what is used for

Cannabis hemp oil 10% CBD is oil extract from Cannabis hemp oil 10% CBD or hemp plant that is an annual grassy 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.

Cannabis hemp oil 10% CBD 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).

Cannabis hemp oil 10% CBD may also 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 cells construction, metabolic processes, maintaining the function of many systems and complete improvement of the general health condition.

Cannabis hemp oil 10% CBD contains THC (9-delta tetrahydrocannabinol) in amount less than 0,2%.

Cannabis hemp oil 10% CBD can help the body in conditions with malignant diseases, multiplex sclerosis, HIV and epileptic syndromes in childhood. Cannabis hemp oil 10% CBD 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 hemp oil 10% CBD

- 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 in prevention of cardiovascular diseases: helps in regulation of blood pressure, improves heart function, has cardio protective 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.

2. Information that should be known before taking borderline product Cannabis hemp oil 10% CBD

Do not take/use Cannabis hemp oil 10% CBD if you:

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

Take special care with Cannabis hemp oil 10% CBD

There are not known conditions, diseases or taking other medicines where Cannabis hemp oil 10% CBD should be applied with care.

Pregnancy and breastfeeding

Do not use Cannabis hemp oil 10% CBD if you are pregnant or breastfeeding.

Effects on psychophysical abilities

Cannabis hemp oil 10% CBD does 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 the use of Cannabis hemp oil 10% CBD

Important information about some ingredients of Cannabis hemp oil 10% CBD

There are no data about intolerance of any of the ingredients of Cannabis hemp oil 10% CBD

Taking/using other medicinal products

There are not known effects of taking other medicinal products at the same time with Cannabis hemp oil 10% CBD

Cannabis hemp oil 10% CBD should not be taken at the same with alcohol or illegal substances.

3. Information on proper use of borderline product Cannabis hemp oil 10% CBD

Cannabis hemp oil 10% should be taken by dropping under the tongue.
It should be shaken well before use. Before use, the bottle with Hemp oil should be heated by holding it with the palms and should be well shaken.



Adults:

Cannabis hemp oil 10% CBD is used 2 times daily.
5 drops are dropped under the tongue and are kept about 60 seconds before swallowing.

Children up to 14 years of age

Cannabis hemp oil 10% is used once daily.
1-2 drops are dropped under the tongue and maintain about 60 seconds before swallowing.
The dose may be increased upon recommendation by physician.
Cannabis hemp oil 10% CBD is suitable for people with diabetes and population on vegetarian nutrition.

4. Information about possible side effects of borderline product Cannabis hemp oil 10%

There are not known side effects of Cannabis hemp oil 10% CBD.
In case of signs of hypersensitivity, the use of Cannabis hemp oil 10% CBD should be discontinued!

5. Information about storage and expiry date of borderline product Cannabis hemp oil 10%

Cannabis hemp oil 10% CBD should be kept out of reach of children!
The expiry date of Cannabis hemp oil 10% CBD is stated on the package.
Cannabis hemp oil 10% CBD should not be used after the expiry date!
Cannabis hemp oil 10% CBD should be stored at a temperature of 25°C protected from direct light, heat and humidity.
Do not freeze.

6. Additional information about borderline product Cannabis hemp oil 10% CBD

What Cannabis hemp oil 10% CBD contains?

Cannabis hemp oil 10% CBD, 10 ml contains:
-CBD (Cannabidiol extracted from Cannabis plant) 1000mg
-Olive oil up to 10 ml

What Cannabis hemp oil 10% CBD looks like and package size

Cannabis hemp oil 10% CBD is in dark glass bottle of 10 ml, with a dropper and patient information leaflet in carton box.

Marketing Authorization Holder of Cannabis hemp oil 10% CBD

REPLEK FARM Ltd. Skopje
Kozle st.188, 1000 Skopje, R. N. Macedonia

Manufacturer of Cannabis hemp oil 10% CBD

REPLEK FARM LTD Skopje
Kozle st. 188, 1000 Skopje, R. N. Macedonia

Number and date of registration into the Register for borderline products

11-6516/4 from 06.09.2016