

PATIENT INFORMATION LEAFLET

CANNABIS BIO Oil solution in hemp seed oil 20% CBD, spray, 10 ml (2000 mg CBD/ 10 ml)

Please read this leaflet carefully before you start taking this borderline product because it contains important information for you.

-This borderline product is available without prescription for treatment (relieve) of health problems for which you do not need physician advice. However, CANNABIS BIO 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 BIO and what is used for*
- 2. What you need to know before taking the borderline product CANNABIS BIO*
- 3. How to take borderline product CANNABIS BIO*
- 4. Possible side effects*
- 5. Storage and shelf life of borderline product CANNABIS BIO*
- 6. More information*

1. What is borderline product CANNABIS BIO and what is used for

Cannabis BIO is oil solution, spray for oral use, that contains oily extract from hemp plant (Cannabis) and hemp seed oil. The oil solution is with proven absence of pesticides and herbicides in the product.

The oily extract is produced with extraction from hemp plant (Cannabis), which is carried out at low temperature without use of organic solvents that provides the highest quality of the oil extract. The extract contains cannabinoids, primarily CBD (Cannabidiol), as well as CBN (Cannabinol), CBG (Cannabigerol) and other similar compounds.

Cannabinoids bind to the CB1 and CB2 receptors of the endocannabinoid system in the human body and may have immunomodulating effect (improving the immune system) and other positive effects for the general health condition.

Hemp seed oil in Cannabis BIO is one of the few natural herbal oils, suitable for everyday use in nutrition that contains essential omega-6 fatty acids (linoleic - LA and gamma-linoleic acid - GLA) and omega-3 fatty acids (alpha linoleic - ALA and stearidonic acid - SDA) in a ratio 3:1. Maintaining the balance of this ratio in nutrition is important for prevention of occurrence of inflammatory, cardiovascular, skin diseases and other health conditions.

This oil contains all the essential amino acids in a balanced ratio, also contains minerals, oligoelements, vitamins, as well as phytosterols and tocopherols.

Cannabis BIO product from oily extract from hemp plant and hemp seed oil, may contain terpens, flavonoids, glycosides, pigments, alkanes, nitrogen compounds, essential amino acids in a balanced ratio, magnesium, manganese, iron, zinc, potassium, vitamins (A, B1,

B2, B3, B5, B6, C, D, E, F) and significant amounts of phytosterols and tocopherols (from Vitamin E complex), that are important in cells construction and normal metabolic and physiological processes in human body.

The complex compounds of the oily extract and hemp seed oil in Cannabis BIO spray have “entourage” effect, i.e. show synergistic and mutual complementary action, which provides oil solution with favorable effect on the function on many systems in human body and general health condition.

Cannabis BIO contains THC (9-delta tetrahydrocannabinol) in amount less than 0,2%.

What is this borderline product CANNABIS BIO used for

Cannabis BIO can help the body in conditions with malignant diseases, multiple sclerosis, HIV and epileptic syndromes in childhood.

Cannabis BIO is not a substitute for standard prescribed therapy and especially it is not a substitute for standard therapy of above mentioned diseases.

The positive effects from taking Cannabis BIO are manifested in:

- Conditions of stress, anxiety, nervousness, depression, muscle spasms;
- Nausea and vomiting, especially during chemo or radiation therapy in malignant diseases;
- Impaired balance of intestinal flora;
- Chronic pain (mainly pain associated with nervous system, for example caused by damaged nerve, phantom pain, facial neuralgia or chronic pain which remains after recovery from shingles).

It can be used for:

- Prevention of cardiovascular diseases: helps in regulation of the blood pressure, improves heart function and has cardio protective effect;
- Helps in regulation of the elevated concentrations of lipids and cholesterol levels in the blood (increased level of fats in the blood);
- Helps in regulation of elevated glycaemia (increased level of glucose) in the blood, especially for people with diabetes;
- Improving general health condition in patients with Parkinson disease;
- Attenuation of cognitive impairment in patients with Alzheimer disease;
- Positive effect on development of Crohn’s disease symptoms;
- Alleviation of inflammation and pain in patients with Rheumatoid arthritis.

2. Information that should be known before taking borderline product CANNABIS BIO

Do not take/use Cannabis BIO if you:

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

Take special care with Cannabis BIO

There are not known conditions, diseases or taking other medicines where Cannabis BIO should be applied with care.

Pregnancy and breastfeeding

Do not use Cannabis BIO if you are pregnant or breastfeeding.

Effects on psychophysical abilities

Cannabis BIO 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 BIO.

Important information about some ingredients of Cannabis BIO

There are no data about intolerance of any of the ingredients of Cannabis BIO.

Taking/using other medicinal products

There are not known effects of taking other medicinal products at the same time with Cannabis BIO.

Cannabis BIO should not be taken at the same time with alcohol or illegal substances.

3. Information on proper use of borderline product CANNABIS BIO

Cannabis BIO oil solution in a form of spray provides simple and quick use.

Cannabis BIO spray is intended for sublingual use (it is sprayed under the tongue).

Using Cannabis BIO under the tongue enables direct absorption of Cannabidiol (CBD) in the blood and faster providing of higher concentrations of CBD in the systemic circulation.

The advantage of spraying under the tongue is the possibility of simpler dose adjustment while gradually increasing the dose (if necessary).

Single dose of spray has volume of 200 µl with which, approximately 40 mg of CBD is provided.

It should be shaken well before use.

Cannabis BIO is sprayed under tongue with simple pressure on the pump and after spraying, it is kept for 60 seconds before swallowing.

While using Cannabis BIO spray under the tongue, specific taste originating from natural components of Cannabis plant may be felt.

Adults and children over 14 years of age: one spray, once or twice daily.

Children under 14 years of age: it is recommended one spray once daily.

Food does not affect the use of Cannabis BIO.

The dose may be increased upon recommendation by physician.

Cannabis BIO does not contain gluten and lactose.

It is suitable for population on vegetarian and/or vegan nutrition.

Cannabis BIO may be used by people with diabetes.

4. Information about possible side effects of borderline product CANNABIS BIO

There are not known side effects of Cannabis BIO.

In case of signs of hypersensitivity, the use of Cannabis BIO should be discontinued!

5. Information about storage and expiry date of the borderline product CANNABIS BIO

Cannabis BIO should be kept out of reach of children!

The expiry date of Cannabis BIO is stated on the package.

Cannabis BIO should be stored in original package, at a temperature up to 25°C, protected from direct light, heat and humidity.
Do not freeze.

6. Additional information about the borderline product CANNABIS BIO

What Cannabis **BIO** contains?

Cannabis BIO oil solution, spray contains:

- 2000 mg CBD (Cannabidiol extracted from Cannabis plant);
- Hemp seed oil up to 10 ml.

What Cannabis **BIO** looks like and package size?

Cannabis BIO oil solution is in dark glass bottle of 10 ml, dosing pump with plastic transparent cap and patient information leaflet in carton box.

Marketing Authorization Holder of Cannabis **BIO**

REPLEK FARM Ltd. Skopje

Kozle st. 188, 1000 Skopje, R.N. Macedonia

Manufacturer of Cannabis **BIO**

REPLEK FARM Ltd. Skopje

Kozle st. 188, 1000 Skopje, R.N. Macedonia

Number and date of registration into the Register for borderline products:

11-9317/2 from 17.10.2018