

## PATIENT INFORMATION LEAFLET

### CANNABIS femme vagitories 50 mg

#### CBD (Cannabidiol)

**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 femme vagitories 50 mg 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 femme vagitories 50 mg and what is used for*
- 2. What you need to know before taking borderline product CANNABIS femme vagitories 50 mg*
- 3. How to take borderline product CANNABIS femme vagitories 50 mg*
- 4. Possible side effects*
- 5. Storage and shelf life of borderline product CANNABIS femme vagitories 50 mg*
- 6. More information*

#### **1. What is borderline product CANNABIS femme vagitories 50 mg and what is used for**

Cannabis femme vagitories 50 mg contain CBD hemp oil that is oil extract from annual grassy plant cannabis or hemp. 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 terpenes, 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%.

Cannabis femme vagitories 50 mg have positive effect on woman's intimate health, due to anti-inflammatory and positive effect of CBD (Cannabidiol) on the immune system.

Cannabis femme vagitories 50 mg have favorable effect:

- on vaginal mucosa resistance to vaginal infections in stress and reduced immunity,
- on vaginal inflammations followed by increased secretion,
- on vaginal mucosa changes followed by itching and pain,

-on circulation and epitelization improvement of damaged vaginal mucosa.

## **2. Information that should be known before taking borderline product CANNABIS femme vagitories 50 mg**

*Do not take/use CANNABIS femme vagitories 50 mg if you:*

- are hypersensitive to any ingredient of vagitories;
- are pregnant or breastfeeding.

*Take special care with CANNABIS femme vagitories 50 mg*

There are not known conditions, diseases or taking other medicines where CANNABIS femme vagitories 50 mg should be applied with care.

*Pregnancy and breastfeeding*

Do not use CANNABIS femme vagitories 50 mg if you are pregnant or breastfeeding.

*Effects on psychophysical abilities*

CANNABIS femme vagitories 50 mg 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.

*Important information about some ingredients of CANNABIS femme vagitories 50 mg*

There are no data about intolerance of any of the ingredients of CANNABIS femme vagitories 50 mg.

*Taking/using other medicinal products*

There are not known effects of taking other medicinal products at the same time with CANNABIS femme vagitories 50 mg.

## **3. Information on proper use of borderline product CANNABIS femme vagitories 50 mg**

CANNABIS femme vagitories 50 mg are intended for vaginal use only.

Adults

One CANNABIS femme vagitory 50 mg is inserted deep into the vagina once daily before going to bed.

After insertion of the vagitory, 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 femme vagitories 50 mg**

There are not known side effects of CANNABIS femme vagitories 50 mg.

In case of signs of hypersensitivity, use of CANNABIS femme vagitories 50 mg should be discontinued!

## **5. Information about storage and expiry date of borderline product CANNABIS femme vagitories 50 mg**

CANNABIS femme vagitories 50 mg should be kept out of reach of children!

The expiry date of CANNABIS femme vagitories 50 mg is stated on the package.

CANNABIS femme vagitories 50 mg v should not be used after the expiry date!

CANNABIS femme vagitories 50 mg should be stored at a temperature up to 25°C in original package.

## **6. Additional information about borderline product CANNABIS femme vagitories 50 mg**

### ***What CANNABIS femme vagitories 50 mg contain?***

One CANNABIS femme vagitory 50 mg contains:

-50 mg CBD (Cannabidiol extracted from Cannabis plant)

-Hard fat.

### ***What CANNABIS vagitories 50 mg look like and package size?***

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

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

### ***Marketing Authorization Holder of CANNABIS femme vagitories 50 mg***

**REPLEK FARM Ltd. Skopje**

Kozle st. 188, 1000 Skopje, Republic of Macedonia

### ***Manufacturer of CANNABIS femme vagitories 50 mg***

**REPLEK FARM Ltd. Skopje**

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

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

CANNABIS femme vagitories 50 mg x 5: 11-4598/3 from 03.05.2017

CANNABIS femme vagitories 50 mg x 10: 11-4598/2 from 03.05.2017