

Patient information leaflet

Cannabis ointment with natural hemp extract with Vitamin E (100 mg CBD/ 50 g ointment)

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 ointment with natural hemp extract with Vitamin E 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 ointment with natural hemp extract with Vitamin E and what is used for*
- 2. What you need to know before taking borderline product Cannabis ointment with natural hemp extract with Vitamin E*
- 3. How to take borderline product Cannabis ointment with natural hemp extract with Vitamin E*
- 4. Possible side effects*
- 5. Storage and shelf life of borderline product Cannabis ointment with natural hemp extract with Vitamin E*
- 6. More information*

1. What is borderline product Cannabis ointment with natural hemp extract with Vitamin E and what is used for

Cannabis ointment with natural hemp extract with Vitamin E contains oil extract from cannabis or hemp plant obtained with extraction carried out at low temperature without using of organic solvents, with proven absence of pesticides and herbicides.

The hemp oil extract contains cannabinoids and may contain terpens, omega fatty acids (omega-3, omega-6, omega-9), flavonoids, phytosterols, pigments, amino acids and vitamins (A, B1, B2, B6, C, D).

The hemp oil extract contains THC (9-delta tetrahydrocannabinol) in amount less than 0,2%. Cannabinoids, especially CBD (Cannabidiol), bind to the receptors from the endocannabinoid system in the skin especially to the adequate cell receptors from the surface layer of the skin (epidermis), the cells of the sebaceous glands and nerve endings in the skin, thus achieving their anti-inflammatory and soothing effect.

Cannabidiol in Cannabis ointment with natural hemp extract with Vitamin E based on several conducted studies may:

- have local anti-inflammatory effect,
- reduce the pain and itching ,
- affect secretion of the sebum from the sebaceous glands (especially in skin with increased secretion of the sebaceous glands associated with age and hormonal status),
- reduce the excessive cell growth (hyperkeratosis).

Cannabis ointment with natural hemp extract with Vitamin E contains Vitamin E that has beneficial effect over epithelialization, regeneration and maintenance of the skin tonus

2. Information that should be known before taking borderline product Cannabis ointment with natural hemp extract with Vitamin E

Do not take/use Cannabis ointment with natural hemp extract with Vitamin E if you:
-are hypersensitive to any ointment ingredient.

Take special care with Cannabis ointment with natural hemp extract with Vitamin E

There are not known conditions, diseases or taking other medicines where Cannabis ointment with natural hemp extract with Vitamin E should be applied with care.

Pregnancy and breastfeeding

Do not use Cannabis ointment with natural hemp extract with Vitamin E if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, consult your physician or pharmacist before using Cannabis ointment with natural hemp extract with Vitamin E.

Effects on psychophysical abilities

Cannabis ointment with natural hemp extract with Vitamin E 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.

Important information about some ingredients of Cannabis ointment with natural hemp extract with Vitamin E

There are no data about intolerance to any of the ingredients of Cannabis ointment with natural hemp extract with Vitamin E.

Taking/using other medicinal products

There are not known effects of taking other medicinal products at the same time with Cannabis ointment with natural hemp extract with Vitamin E.

3. Information on proper use of borderline product Cannabis ointment with natural hemp extract with Vitamin E

Cannabis ointment with natural hemp extract with Vitamin E is intended for external use only.

The skin has to be cleaned before using Cannabis ointment with natural hemp extract with Vitamin E.

Cannabis ointment with natural hemp extract with Vitamin E is applied in a thin layer on the affected part of the skin twice daily.

You should avoid contact with eyes during the use of Cannabis ointment with natural hemp extract with Vitamin E.

Cannabis ointment with natural hemp extract with Vitamin E contains ingredients that can smear the surface on which the product is applied.

4. Information about possible side effects of borderline product Cannabis ointment with natural hemp extract with Vitamin E

There are not known side effects of Cannabis ointment with natural hemp extract with Vitamin E.

In case of signs of hypersensitivity, use of Cannabis ointment with natural hemp extract with Vitamin E should be discontinued!

5. Information about storage and expiry date of borderline product Cannabis ointment with natural hemp extract with Vitamin E

Cannabis ointment with natural hemp extract with Vitamin E should be kept out of reach of children!

The expiry date of Cannabis ointment with natural hemp extract with Vitamin E is stated on the package.

Cannabis ointment with natural hemp extract with Vitamin E should not be used after the expiry date!

Cannabis ointment with natural hemp extract with Vitamin E should be stored at temperature up to 25°C in original package.

6. Additional information about borderline product Cannabis ointment with natural hemp extract with Vitamin E

What does Cannabis ointment with natural hemp extract with Vitamin E contain?

50 g Cannabis ointment with natural hemp extract with Vitamin E contains approximately 455 mg natural hemp extract which provides 100 mg CBD (Cannabidiol extracted from Cannabis plant).

- other ingredients: paraffin white soft, paraffin liquid, isopropyl myristate, beeswax white, tocopheryl acetate (Vitamin E).

Cannabis ointment with natural hemp extract with Vitamin E does not contain artificial colors and parabens.

What Cannabis ointment with natural hemp extract with Vitamin E looks like and package size?

Cannabis ointment with natural hemp extract with Vitamin E is homogenous, pale to darker yellow-greenish ointment, easy to apply with characteristic odor.

The box contains tube with 50 g ointment and patient information leaflet.

Marketing Authorization Holder of Cannabis ointment with natural hemp extract with Vitamin E

REPLEK FARM Ltd. Skopje

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Manufacturer of Cannabis ointment with natural hemp extract with Vitamin E

REPLEK FARM Ltd. Skopje

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

11-11609/2 from 14.12.2016

