

PACKAGE LEAFLET: INFORMATION FOR THE USER

KANSEN

20 mg / g (2%), vaginal cream

CLOTRIMAZOLE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What Kansen is and what it is used for
2. Before you use Kansen
3. How to take Kansen
4. Possible side effects
5. How to store Kansen
6. Further information

1. WHAT KANSEN IS AND WHAT IT IS USED FOR

Kansen vaginal cream 2% for the active substance has clotrimazole.
Clotrimazole is antifungal medicine.

How Kansen works?

Clotrimazole works by damaging the cytoplasmic membrane of the fungi and thus prevents their further growth and multiplication.

When to use Kansen?

Vaginal tablets are used to treat vaginal candidiasis.

Vaginal candidiasis is a common infection caused by fungi.

Candida is a fungus that normally inhabit the vagina without causing any changes. However, in certain circumstances, an infection of the vagina may develop, which can be extended to the environment (ie. The labia).

Common symptoms of infection are:

- Itching of the vagina and vulva (labia)
- Redness and swelling of tissues of the vagina and vulva (labia)
- Pain in the vagina
- whitish vaginal discharge, odorless

It may be that you have a vaginal candidiasis, and you do not have all of these symptoms.

If you have this infection for the first time, talk to your doctor before starting treatment.

2. BEFORE YOU USE KANSEN

Warn your doctor if you are taking other medicines, have a chronic disease, a disorder of metabolism, you're hypersensitive to some of the medications, or have had an allergic reaction to some of them.

Do not use Kansen:

- if you are allergic to clotrimazole or any other component of this preparation. This also applies to your baby. If you are not sure, ask your doctor or pharmacist.

Do not use Kansen Vaginal cream 2% if you have the following:

- vaginal bleeding in the period outside of the menstrual cycle
- Profuse vaginal bleeding or blood stains in the vaginal secretions.
- ulcerations, bubbles or sores on the vagina or vulva (labia)
- Pain in the lower abdomen
- Pain and difficulty when urinating
- side effects associated with the therapy such as redness, irritation or swelling
- nausea or vomiting
- diarrhea
- unpleasant smell of vaginal secretions

In this case Kansen vaginal cream 2% is not the right medicine you.

If you are unsure whether you have vaginal candidiasis, consult a physician.

Take special care with Kansen:

Tell your doctor or midwife if you are pregnant, breastfeeding or trying to get pregnant before you start to use Kansen vaginal cream 2%. It is necessary to carefully follow their instructions.

Before using this product consult your doctor if:

- You had more than two vaginal infection in the last 6 months
- you or your sexual partner ever had a sexually transmitted disease
- If you are under 16 or over 60 years
- If you have ever had an allergic reaction to Kansen or other antifungal medications.

Like other vaginal preparations Kansen vaginal cream 2% may reduce the effectiveness of the rubber contraceptives, such as condoms or the diaphragm. Therefore, it is necessary to use other, alternative means of protection, at least 5 days after cessation of treatment with this medicine.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Epidemiological studies indicate that clotrimazole does not lead to unintended consequences on pregnancy, and does not affect the health of the fetus / newborn.

Kansen vaginal cream 2% can be used during pregnancy, but only under the control of the doctor or midwife.

During pregnancy it is not advisable to use an applicator to avoid possible mechanical injuries. During pregnancy, it is recommended that therapy includes vaginal tablet without applicator or that vaginal cream therapy is carried out by a doctor.

Using other medicines

It should be borne in mind that this information may also apply to medicines that you no longer use, as well as the medication that you plan to take in the future. Tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription.

What you need to know about excipients contained in the drug Kansen vaginal cream 2%

This preparation contains as auxiliary substances cetyl and stearyl alcohol. They may cause local skin reactions (such as contact dermatitis).

3. HOW TO TAKE KANSEN

If you think that the drug Kansen Vaginal tablet has too weak or too strong effect on your body, you should contact your doctor.

Kansen vaginal cream 2% is administered intra-vaginally, as deep as possible into the vagina.

Adults

Squeeze out one filling of the applicator (about 5 g), preferably at bedtime, for 3 consecutive days. If necessary, repeat the treatment.

Children

The children should not use this preparation.

Use of Kansen vaginal cream 2% during the menstrual period is not recommended.

How to use the medicine:

1. First, clip of the disposable applicator should be pulled out as much as possible (until the end).
2. Open the tube, set the applicator, keep it firmly fixed and gently fill the applicator by pressing the tube.
3. Remove the applicator tube, enter it as deep into the vagina as possible (preferably lying on the back with legs slightly bent) and by pushing the plunger empty it out.
4. Throw away the empty applicator.

In each application it is necessary to take a new single-use applicator.

To avoid reinfection follow these instructions:

- wear cotton underwear and loose clothing. Wearing tight clothes, clothing that tightens as tight jeans and synthetic fabrics favors the creation of conditions for fungal growth and the emergence of infection.
- Wash daily
- after going to the toilet, wipe in the direction from front to back, otherwise the infection may move from the intestine to the vagina
- Maintain regular hygiene of toilets

- Avoid the use of soaps containing perfumes, and vaginal deodorants
- Avoid using a sponge or flannel cloth with bathing and swimming in hot water with perfumed oils; If you have a vaginal infection it is most suitable to swim in warm water with a little salt in it.

If you are still worried or have concerns, consult your doctor.

Kansen vaginal cream 2% is only for vaginal use. This preparation should not be swallowed or put in mouth. If you happen to accidentally swallow vaginal tablet, immediately contact your doctor or nearest hospital emergency.

Your doctor will advise you how long to take your medicine KANSEN vaginal cream 2%. Do not interrupt treatment because this will not cure the infection.

If you use more Kansen than you should

If you take more KANSEN than you should immediately talk to your doctor or pharmacist!

If you forget to use Kansen

If you forget to apply the cream, do it as soon as you can and then continue with the regular use of it.

4. POSSIBLE SIDE EFFECTS

Rarely, you may feel a tingling sensation or irritation immediately after use of vaginal tablets. Kansen vaginal cream 2% may cause adverse reactions that are similar to the symptoms of the infection itself. If redness, burning, pain, itching, or swelling worsen, it is necessary to consult a doctor as soon as possible.

Like all medicines, Kansen vaginal cream 2% may cause allergic reactions. If you are allergic to Kansen vaginal cream, the reaction will occur soon after use. Local symptoms of allergic reactions are similar to those described above. Very rarely generalized allergic reaction that is accompanied by rash, nausea, malaise, facial swelling, low blood pressure, diarrhea and shortness of breath can occur. If you experience any of these reactions, contact your doctor.

If you feel in any way undesirable reaction to this medicine, consult your doctor

5. How to store Kansen

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store in the original carton
- Do not use Kansen after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Kansen contains

Active ingredients:

One gram of a vaginal cream contains 20 mg of clotrimazole.

Other ingredients: Sorbitanstearat; Polysorbate 60; cetaceun; cetyl alcohol; stearyl; octyldodecanol; benzyl alcohol; Purified water.

Packing

Aluminium tube with 20 g of cream and 3 applicators in a cardboard box.

The regime of dispensing

The drug is issued on prescription.

Manufacturer

Zdravlje Ltd.
Vlajkova 199, Leskovac, Serbia

The manufacturer of a medicinal product

Zdravlje Ltd.
Vlajkova 199, Leskovac, Serbia