

PACKAGE LEAFLET: INFORMATION FOR THE USER

KANSEN

10 mg / g (1%), 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 cream, 1% the active substance of this medicine is 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?

Kansen cream 1% is used in the treatment of fungal infections of the skin such as infection known as "tinea", athlete's foot, diaper dermatitis caused by a fungus, fungal intertriginous infection (infection of the flexible surfaces).

Kansen cream 1% can be used to release the symptoms of irritation of the vulva (labia) or penis, when the infection is caused by Candida, ie. Kansen cream 1% is used in the treatment of Candida vulvitis, and can be used with the sexual partner (balanitis) to prevent re-infection.

If you are unsure whether you (or your baby, in case of diaper dermatitis) have a yeast infection, consult your doctor or pharmacist.

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.

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 cream 1%. It is necessary to carefully follow their instructions.

Kansen cream 1% may reduce the effectiveness of the rubber contraceptives, such as condoms or the diaphragm. If you apply the cream to the vulva (labia) or penis, it is necessary to use other, alternative means of protection, for at least 5 days after cessation of therapy.

Kansen cream 1% is only for external use, it should not be put in the mouth or swallowed. If you accidentally swallow Kansen cream 1%, immediately contact your doctor.

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.

Clotrimazole can be used during pregnancy, but only under the control of the doctor or midwife

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 Kansen

Excipients of this preparation are 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 has too weak or too strong effect on your body, you should contact your doctor.

Apply Kansen cream 1% 2-3 times a day, in a thin layer, gently and evenly to the affected region.

If the feet are affected by the infection, before applying Kansen cream 1%, you need to wash your feet, and wiping them well (dry), especially between the toes.

Length of the treatment depends on the type of the infection. In principle, the treatment duration is of 2 to 4 weeks.

Symptoms such as itching and pain recede a few days after the start of therapy, and the withdrawal of redness and flaking takes more time.

If symptoms persist contact your doctor

Your doctor or pharmacist can advise you to include anti-fungal powder into the therapy, especially for the treatment of feet infection • "athlete's foot".

The efficacy of treatment will increase if you follow the following instructions:

- Although you feel itching in the affected region, try to refrain from scratching. Scratching can damage the surface of the skin. Damaged skin surface favors further expansion of the infection;
- the affected region should be always clean, dry and not exposed to excessive friction

Recommendations for treatment of vulvitis (infection of the labia) and balanitis (infection of the glans penis)

Rub Kansen cream into the environment, and the entrance to the vagina, 2-3 times a day. At the same time it is necessary to use the preparations for the treatment of an internal (vaginal) infection.

Treatment should continue until symptoms subside. Contact your doctor if your symptoms do not subside after seven days of the therapy.

If your sexual partner is treated by this cream, it is necessary that the cream is applied to the glans (head) of the penis 2-3 times a day. The treatment lasts up to two weeks.

If you use more Kansen than you should

If you take more KANSEN cream than you should immediately contact your doctor or pharmacist!

If you forget to use Kansen

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

4. POSSIBLE SIDE EFFECTS

Rarely, you or your baby can feel a burning sensation or irritation immediately after applying a cream. Very rarely, Kansen cream can cause adverse reactions that are similar to the symptoms of the infection itself. If redness, burning, pain, itching, hives and swelling worsen, it is necessary to immediately contact your doctor.

Like all medicines, Kansen 1% cream may cause allergic reactions. If you or your baby are allergic to Kansen cream, reactions will occur shortly after applying a cream. Local symptoms of allergic reactions are similar to those described above.

If you or your baby experience any of these reactions, or otherwise undesirable react to this medicine, contact 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. Expiry date: 5 years

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 the cream contains 10 mg of clotrimazole

- Other ingredients: sorbitan stearate; polysorbate 60; cetaceun; cetyl alcohol; stearyl alcohol; octyldodecanol; benzyl alcohol; Purified water

Packing

Kansen cream 1% • aluminum tube with 20 g cream, 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