

PACKAGE LEAFLET: INFORMATION FOR THE USER

KAMISTAD

(20 mg + 185 mg) / g oromucosal gel

LIDOCAINE HYDROCHLORIDE, EXTRACT OF CHAMOMILE FLOWER

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

1. WHAT KAMISTAD IS AND WHAT IT IS USED FOR

KAMISTAD gel contains Lidocaine and liquid extract of chamomile (*Matricaria recutita* L.). This medicine belongs to the group of medicines for the topical treatment of oral mucosa. It is intended for the treatment of the mild inflammation of the gums and oral mucosa.

2. BEFORE YOU TAKE KAMISTAD

Do not take KAMISTAD

- If you are allergic to lidocaine or other amide local anesthetics, chamomile or any of the other ingredients of this medicine (see section 6. "Further information")

Take special care with KAMISTAD

Kamistad should not come into contact with eyes or open wounds. Wash your hands well after applying Kamistad.

Children

Kamistad should not be used in children younger than 12 years, because no sufficient number of studies has been conducted in children of this age.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

There are no available data on interactions with other medicines within the recommended dosage in this leaflet.

Taking KAMISTAD with food and drink

Not applicable.

Pregnancy and breastfeeding

Before you start taking any medication, consult your doctor or pharmacist.

If you are pregnant or breast-feeding your baby, think you are pregnant or planning to become pregnant, contact your doctor or pharmacist for advice before taking medicine.

Kamistad should not be used in pregnant women and during breastfeeding, because no sufficient number of studies has been conducted.

Driving and using machines

KAMISTAD should not affect your ability to drive and use machines.

Important information about some of the ingredients of KAMISTAD

Benzalkonium chloride is an irritant, changes on the skin may occur.

3. HOW TO TAKE KAMISTAD

If you are not sure how to take the medicine, ask your doctor or pharmacist for advice.

Take your medicine according to these instructions (unless your doctor tells you otherwise).

Recommended dose is:

Adults and children over 12 years

Apply approximately ½ cm of the gel three times a day.

Method of administration

The gel is applied to the inflamed place, and it is gently rubbed.

The gel is intended for application to the mucosa of the mouth, take care not to swallow.

Length of application

If your symptoms worsen or do not improve after 7 days, or if the signs of inflammation are often repeated, contact your doctor.

If you take more KAMISTAD than you should

If you take more than the recommended dose or if someone else accidentally takes your medicine, or you accidentally swallow greater amount of the gel, immediately contact your doctor, pharmacist or nearest hospital.

If you forget to take KAMISTAD

If you forget a dose, apply the missed dose of cream as soon as you remember and then continue on the regular schedule. Do not double the dose at any time to make up the missed dose.

If you stop taking KAMISTAD mg

Please do not stop your treatment with KAMISTAD mg without consulting your doctor first. If you have any further questions, contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, KAMISTAD can cause side effects, although not everybody gets them.

Uncommon (can occur in more than 1 per 100 patients taking the medicine):

Transient mild stinging may occur after application of the gel.

Very rare (may occur with more than 1 in 10 000 patients taking the medicine):

Since this preparation contains lidocaine, cinnamon bark oil and chamomile extract, allergic reactions may occur (eg. Contact allergy). These reactions can also occur in patients who are hypersensitive to plants of the family Asteraceae and Peruvian balsam (due to cross-reactions).

Since Kamistad gel contains benzalkonium chloride, it may cause irritation of the skin during the application of the medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE KAMISTAD

Keep out of the reach and sight of children.

Do not store above 30 °C.

Do not use KAMISTAD after the expiry date which is stated on the label, 5 years from the date of manufacture. After opening the product is stable for 12 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION***What KAMISTAD contains***

The active substances are:

The active substances are lidocaine hydrochloride and liquid extract of chamomile (1: 4-5).

1 g of gel contains 20 mg of lidocaine hydrochloride and 185 mg of liquid extract of chamomile (1: 4-5).

The other ingredients are:

- Benzalkonium chloride 50% solution
- 96% ethanol
- formic acid
- Carbomer 980
- Saccharin sodium
- trometamol
- Purified water
- cinnamon oil

What KAMISTAD looks like and contents of the pack

Kamistad, (20 mg + 185 mg) / 1 g
Yellowish-brown gel.

Kamistad, (20 mg + 185 mg) / 1 g
Aluminum tube with HDPE cap of 10 g and 20 g.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka
Novakovići b.b., Banja Luka, Bosnia and Herzegovina

Manufacturer of the medicinal product

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