

PATIENT INFORMATION LEAFLET

KLOROBEN Oral Rinse

For mouth rinse.

- **Active substances:** 100 ml of solution contains 120 mg (12%) of chlorhexidine gluconate and 150 mg (15%) of benzidineamine hydrochloride
- **Excipients:** Polysorbate 20, Sorbitol (70%), propylene glycol, peppermint essence, sucralose, ecocool MP (flavor), Quinoline yellow, Patent V blue, Citric acid monohydrate, Sodium Citrate dehydrate, Purified water.

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 further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
- Tell your doctor if you go to a doctor or the hospital when you use this medicine.
- Follow strictly to what is written in these instructions. Do not use **high or low** doses other than the recommended dose for the medication.

What is in this leaflet:

- 1. What KLOROBEN is and what it is used for***
- 2. Before you use KLOROBEN***
- 3. How to use KLOROBEN***
- 4. Possible side effects***
- 5. How to store KLOROBEN***

Titles are included.

1. WHAT KLOROBEN IS AND WHAT IT IS USED FOR?

- KLOROBEN is an oral preparation used in the regional oral treatment.
- KLOROBEN is a green color, with sweetish sour taste, refreshing mint smelling and clear solution. In amber pet bottles of 200 ml and in carton boxes with scales of 2.5, 3, 5, 7.5, 10 and 15 ml. Each box contains one bottle.
- KLOROBEN contains chlorhexidine gluconate, which is an antimicrobial active substance, and benzimidamine HCl, which is belonging to a non-steroidal

antiinflammatory drugs, which is used for the treatment of pain and inflammation and also as local anesthetic effect(enabling the region to feel numb) when applied superficially.

- KLOBEN, inflammation of the mouth and throat, inflammation of the gums and inflammation of the mouth, infection of the mouth, inflammation of the pharynx, inflammation of the tonsils and wounds in the mouth
- Prevention of inflammatory microbial diseases in the mouth and throat, relieving the patient's swallowing function and eliminating symptoms in gum disorders
- Before and after the operations in the tissues surrounding the teeth
- After irradiation and cancer drug treatment or inflammation of the intraoral layer due to other causes
- It is used to prevent the layer (dental plaque) of bacteria and food residues around the teeth.

2 What you need to know before you take KLOBEN?

DO NOT TAKE KLOBEN in the following situations

If,

- You have known hypersensitivity to benzidamine and chlorhexidine or other excipients,
- You are pregnant or breastfeeding.

TAKE KLOBEN CAREFULLY in the following situations

- Due to lack adequate clinical studies KLOBEN is not recommended for children younger than 12 years of age.
- Just to shake your mouth, do not swallow
- Use only in the mouth, avoid contact with eyes and ears.
- It can make reversible discoloration on the mouth, tongue and teeth. Tooth staining is harmless and can be minimized by tooth brushing.
- KLOBEN should not be swallowed, should be thrown in the mouth by spitting.
Used without dilution.
- In the cases of inflammation-induced sore throat or sore throat accompanied with inflammation, antibiotics treatment may be recommended by the doctor, in addition to KLOBEN treatment.
- If you have kidney and liver impairment

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking KLOBEN with food and drink

It has no interaction with food and drink in terms of application method.

Pregnancy

Consult your doctor or pharmacist before taking this medicine,

Do not use KLOBEN if you are pregnant.

Tell your doctor or pharmacist immediately if you notice that you are pregnant while you are using this medicine.

Lactation

Consult your doctor or pharmacist for advice before taking this medicine,

Do not use KLOBEN if you are breast-feeding

Driving and using machines

KLOBEN has no negative effects on driving and using machinery.

Important information on some excipients of KLOBEN

If you are not hypersensitive to the excipients in this drug, no adverse effects are expected.

Since this medicinal product contains sorbitol, if you have previously been told by your doctor that you have intolerance to certain sugars, you should consult with your doctor before taking this medicinal product.

Usage with other Drugs

KLOBEN has no known significant interaction with other drugs.

The salts of chlorhexidine, an active ingredient of KLOBEN, are incompatible with soap and other anionic compounds, chloramphenicol (an antibiotic type), some inorganic salts and organic compounds; no interaction with benzydamine is established.

If you are presently using a prescribed or unprescribed drug or have done so recently, please inform your doctor or pharmacist thereof.

3. How to use KLOOROBEN?

Instructions for proper use and dose / application frequency:

The adult dose of KLOOROBEN is 15 mL. It is administered at intervals of 1,5-3 hours during the day.

Application route and method:

KLOOROBEN is for mouth rinsing and gargling. KLOOROBEN is used without dilution.

It is hold for at least 30 seconds in mouth. It is thrown orally after use.

Chlorhexidine in the content of KLOOROBEN decreases the incidence of plaque and gingiva during treatment. If KLOOROBEN is used as an alternative to other oral cleaning practices, the mouth should be rinsed with KLOOROBEN for at least 1 minute.

For minimize the coloring caused by Chlorhexidine in KLOOROBEN, it is suitable to brush the teeth before using.

Different age groups:

Pediatric usage (12 years and over):

Mouthwash is made with 5-15 ml of KLOOROBEN once every 1.5-3 hours for 30 seconds.

It should not be used continuously for more than 7 days.

If burning or stinging occurs, mouthwash should be diluted with water.

Due to the inadequate number of clinical studies, it is not recommended to use KLOOROBEN for children under the age of 12.

Geriatric usage:

No dosage changes are required in the elderly.

Special usage conditions:

Renal Failure /Liver Failure:

Deteriorated renal function: Because the absorbed benzydamine and degradation products are excreted in the urine, the possibility of an all-body effect should be considered in patients with severe renal impairment.

Deteriorated liver function: Because the absorbed benzidamine is destroyed in the liver at high doses, the possibility of an all-body effect should be considered in patients with severe hepatic impairment.

Unless your doctor recommends otherwise follow these instructions.

Please do not forget to take your medicine on time.

Your doctor will tell you how long your treatment with KLOBEN will take. Do not interrupt treatment early because you can not get the desired result.

If you feel that KLOBEN's effect is too strong or too mild consult your doctor or pharmacist.

If you use more KLOBEN than you need to use:

Contact your doctor or pharmacist if you have used KLOBEN in doses more than necessary.

However, in the case of ingestion of KLOBEN by accident, treatment for the symptoms should be done. There is no specific antidote.

If you forget to take KLOBEN

Do not take double dose in order to compensate for the forgotten doses.

Possible effects when treatment with KLOBEN is ended

No effect is expected.

4.What are the possible side effects?

Like other medications, side effects can occur in people known to be sensitive to the ingredients in KLOBEN formula.

Side effects are classified as follows:

Very common (Can be seen in at least one of 10 patients)

Common (Less than one in 10 patients but more than one in 100 patients)

Uncommon (Less than one in 100 patients but more than one in 1000 patients)

Rare (Less than one in 1000 patients but more than one in 10000 patients)

Very rare (Less than one in 10000 patients)

Unknown (Unable to estimate from the available data)

Stop using KLOBEN if any of the following occurs, and immediately notify your doctor or contact the emergency department of your nearest hospital:

- Sudden shortness of breath, skin rash, swelling of the face and/or tongue (anaphylaxis)
- Hypersensitivity reactions (hypersensitivity)
- allergic reactions

These are very serious side effects. If you have any of these side effects, it means you have a serious allergy to KKLOROBEN. You may need emergency medical attention or hospitalization. These very serious side effects are very rare.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:

- Skin reactions due to irritations
- Rash in the mouth
- Throat irritation and cough
- Enlargement of the salivary gland

These are serious side effects. Emergency medical attention may be required. Serious side effects are very rare.

Tell your doctor if you notice any of the following:

Very common:

- Numbness in the mouth tissue

Common:

- Stinging and burning sensation in the mouth
- Nausea, vomiting, retching
- Change in taste
- Staining on teeth and other intraoral surfaces (Teeth staining is harmless and can be minimized by brushing before application)
- Increase in calculus formation

Rare:

- Burning and stinging sensation

Very rare:

- Local (regional) dryness or thirst, tingling
- Cool feeling in the mouth
- Allergic reactions, hypersensitivity (hypersensitivity) and anaphylaxis (sudden shortness of breath, skin rash, swelling of the face and/or tongue)
- Laryngospasm (involuntary muscle contraction in the larynx), bronchospasm (narrowing of the airways)
- Temporary swelling, enlargement of the salivary glands

- Irritation-related skin reactions, itching with rash, hives, photodermatitis (reaction on the skin due to light), dandruff, peeling
- Oral desquamation (exfoliation in the mouth)

Unknown:

- Dizziness, headache, drowsiness
- Pharyngeal irritation (pharyngeal irritation), cough
- dry mouth

These are mild side effects of KKLOROBEN. These side effects disappear when the dose is reduced or treatment is stopped.

Inform your doctor or pharmacist if you encounter any side effects not mentioned in these instructions for use.

5.Storage of KLABOBEN

Keep KLABOBEN in its package out of reach and sight of children.

It should be stored at room temperature below 30°C away from daylight.

Use in accordance with the expiration date.

Do not use KLABOBEN after the expiry date printed on the package.

Do not use KLABOBEN if you notice distortion in the product and/or package.

Do not dispose of expired or unused medicines! Give to collection system determined by Ministry of Environment and Urbanization.

Marketing Authorization Holder:

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