

## PATIENT INFORMATION LEAFLET

### **KLOROBEN oral spray, solution**

**Applied into the mouth and the inner surface of the throat (externally).**

- **Active ingredient:** 1 bottle (30 ml) contains 36 mg chlorhexidine gluconate, 45 mg benzydamine HCl.
- **Excipients:** Polysorbate 20, sorbitol (70%), propylene glycol, quinoline yellow, peppermint essence, sucralose, ecocool MP, patent V blue, citric acid monohydrate, sodium citrate dihydrate, purified water

**Please read the LEAFLET carefully before you start using this medication as it involves important information for you.**

- *Keep this leaflet. You may need to read it again later.*
- *If you have further questions, please consult your doctor or pharmacist.*
- *This medication is prescribed specifically for you; please do not give it to others.*
- *While using this medication if you go to the doctor or hospital, tell your doctor that you are using this medication.*
- *Please follow what is written in this leaflet. Do not use **over or below** the dose recommended for you.*

### **In this leaflet,**

- 1. What is KLOROBEN and what is it used for?***
- 2. Special warnings and precautions for the use of KLOROBEN***
- 3. How is KLOROBEN used?***
- 4. What are the possible side effects?***
- 5. How to store KLOROBEN***

**Headlines are included.**

#### ***1. What is KLOROBEN and what is it used for?***

- KLOROBEN is a clear solution with a green color, sweet and bitter taste, refreshing mint fragrance. KLOROBEN is supplied in white HDPE bottles with pump apparatus, in cardboard boxes. Each box contains 1 bottle.

- KLOOROBEN contains chlorhexidine gluconate an antimicrobial ingredient (which kills microbes or prevents their proliferation) and benzydamine HCl, an ingredient of non-steroid anti-inflammatory drugs family, which is used in the treatment of inflammation, and has local anaesthetic effect (leads to the numbing of the area applied) when applied on the surface.
- KLOOROBEN is used in the inflammation in the mouth and throat mucosa and gingivitis with pain, mouth surface inflammation, pharyngitis, tonsillitis, and mouth sores,
- Prevention of microbial diseases that cause inflammation in the mouth and throat, relief of swallowing function and removal of symptoms in gum disorders
- Before and after interventions on the tissue surrounding the teeth,
- Oral mucositis induced by radiation and cancer medication or other reasons
- Prevention of dental plaque caused by bacteria and food waste around the teeth.

## **2. Things to consider before using KLOOROBEN**

### **DO NOT USE KLOOROBEN in the following situations**

- If you are hypersensitive to benzydamine and chlorhexidine or any one of the ingredients of KLOOROBEN formula, do not use KLOOROBEN.
- If you are pregnant or breast-feeding do not use KLOOROBEN.

### **CAUTION should be exercised when using KLOOROBEN in the following situations**

- If KLOOROBEN contact with eyes, rinse with plenty of water immediately. KLOOROBEN is administered only inside the mouth; avoid contact with eyes and ears.
- Do not swallow KLOOROBEN and remove from mouth by spitting.
- If sore throat caused by bacterial inflammation or coexists with bacterial inflammation, antibiotic therapy may be required in addition to the use of KLOOROBEN.
- If you have kidney and liver disorders, you should use it with caution.
- Do not use it on children under the age of 6 due to the insufficiency of clinical trials.

- KlorobEN can cause reversible staining in the mouth, on the tongue and the teeth. It is recommended that you brush your teeth before administration to minimize staining.

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

#### **Use of KlorobEN with food and drink**

No interaction with food and drinks.

#### **Pregnancy**

*Consult your doctor or pharmacist before using the medication.*

Do not use KlorobEN if you are pregnant.

*If you realise that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

#### **Breast-feeding**

*Consult your doctor or pharmacist before using the medication.*

Do not use KlorobEN if you are breast-feeding.

#### **Driving and using machinery**

KlorobEN has no negative effects on driving and using machinery.

#### **Important information on the excipients in KlorobEN formula**

Since this medicinal product contains sorbitol, if you have already been told by your doctor that you have intolerance to certain sugars, contact your doctor before taking this medicinal product.

#### **Concomitant use with other drugs**

KlorobEN has no known significant drug interactions.

The salts of chlorhexidine, an active ingredient of KlorobEN, are incompatible with soap and other anionic compounds, chloramphenicol (an antibiotic type), some inorganic salts and organic compounds; no drug interactions with benzydamine have been reported.

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

### **3. How is KlorobEN used?**

#### **Instructions for appropriate usage and dose/administration frequency:**

KlorobEN is administered directly on the throat or the inflamed area. The usual dose is 5-10 sprays. If necessary, it can be repeated every 1,5-3 hours.

#### **Administration route and method:**

KlorobEN is used without diluting. KlorobEN should not be swallowed and should be

removed from the mouth by spitting.

Before first use, the pumping button must be pressed several times by holding it away from the face until a regular spray is achieved.

The mouth should be opened widely and spray nose should be inserted into the mouth and administered into the oral cavity. This must be repeated at least 4 times in various areas.

Following the administration the bottle should be stored in its box vertically.

Chlorhexidine, which KLOBEN contains, alleviates the formation of plaque and gingivitis during the treatment. KLOBEN should be kept in the mouth for at least 1 minute if used as an alternative to oral cleaning methods.

In order to minimise the staining caused by chlorhexidine in KLOBEN, it is necessary to brush the teeth before using it.

### **Different age groups:**

#### **Pediatric usage:**

In children above the age of 6, the spray is administered directly on the throat or the inflamed area. The usual dose is 5 sprays. If necessary it can be repeated every 1,5- 3 hours.

KLOBEN is not recommended for children under 6 years of age due to insufficient experience.

#### **Geriatric usage:**

Elderly patients can be administered the same dose with adults.

### **Special use situations:**

#### **Renal/Liver Failure:**

Caution should be exercised while using it on patients with severe kidney or liver failure.

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

### **If you have used more KLOBENs than you should:**

Talk to a doctor or pharmacist immediately if you have used more than you should use from KLOBEN.

Intoxication is not possible when consider the route of administration of the active substance.

However, in the case of ingestion of KLOBEN by accident, your doctor will administer treatment for the symptoms.

### **If you forget to take KLOBEN**

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

### **Effects that may occur when treatment with KLOBEN is terminated**

None.

### **4. What are the possible side effects?**

Like all medicines, people who are sensitive to the ingredients of KLOBEN may have side effects.

Side effects are classified as follows:

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

Common (less than one of 10 but more than one of 100)

Uncommon (less than one of 100 but more than one of 1000)

Rare (less than one of 1000 patients but more than one of 10000 patients)

Very rare (less than one in 10 000 patients may be seen)

Unknown (Unable to estimate from the available data)

**Stop using KLOBEN in the case of one of the following situations and contact your doctor or go to the emergency department of the nearest hospital IMMEDIATELY:**

- Sudden difficulty in breathing, skin rash, swelling in face and/or tongue (anaphylaxis)
- Hypersensitivity reactions
- Allergic reaction

These are very serious side effects. If you have one of these side effects, it means you are seriously allergic to KLOBEN. You may need to take urgent medical care or you may need to be hospitalised. These serious side effects are seen quite rarely.

**If you realise one of the following, contact your doctor or go to the emergency department of the nearest hospital immediately:**

- 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:**

- Temporary sensation decrease in mouth

**Common:**

- Stinging and burning sensation in the mouth

- Nausea

- Vomiting

- Retching

- Change in taste

- Staining on teeth and other oral surfaces (Teeth staining is harmless and can be minimized by brushing prior to 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 (light-induced skin reaction), 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.

*If you experience a side effect other than those mentioned in this leaflet, inform your doctor or pharmacist.*

**5. Storage of KLABOBEN**

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

It should be stored at room temperature below 25°C protect away from daylight.

**Use in accordance with expiration dates**

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

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

***Marketing Authorisation Holder:***

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