

## PATIENT INFORMATION LEAFLET

### **KLORHEX PLUS 2,5 mg/ml + 1,2 mg/ml oral spray, solution**

**It is applied by spraying into the mouth.**

- **Active ingredient:** 30 ml of oral spray contains 0,075 g of flurbiprofen and 0,036 g of chlorhexidine digluconate.
- **Excipients:** Macrogolglycerol hydroxystearate 40, glycerol, saccharin sodium, sorbitol liquid, non-crystalline (70%), ecocool MP, patent blue V, sodium hydrogen carbonate, propylene glycol, purified water

**Before you start using this medicine, carefully read this INSTRUCTIONS FOR USE, because it contains important information for you.**

- *Keep this instruction. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *During the use of this medicine, tell your doctor that you are using this medicine when you go to the doctor or hospital.*
- *Follow exactly what is written in this instruction. Apart from the dose recommended to you about the drug do not use **high or low doses**.*

### **In this Instructions for Use:**

- 1. What is KLORHEX PLUS and what is it used for?***
- 2. Before you use KLORHEX PLUS***
- 3. How to use KLORHEX PLUS?***
- 4. What are the possible side effects?***
- 5. Storage of KLORHEX PLUS***

**Headings are included.**

***1. What is KLOORHEX PLUS and what is it used for?***

KLOORHEX PLUS is an oral preparation used in intraoral regional treatment.

KLOORHEX PLUS is used to prevent microbial diseases that cause inflammation in the mouth and throat, to relieve swallowing function and to relieve symptoms of gingival disorders. It can be used for protection before dental procedures.

KLOORHEX PLUS is presented in 30 ml white HDPE bottle with spray applicator and cardboard box.

***2. Before you use KLOORHEX PLUS***

**DO NOT USE KLOORHEX PLUS in the following situations**

- If you are hypersensitive to flurbiprofen, chlorhexidine or any of the excipients in the product's formula,
- If you are sensitive to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- If you have ever had bronchospasm (difficulty breathing due to bronchial narrowing), a cold (rhinitis) or hives (urticaria) due to the use of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- If you have ulcers (peptic ulcer) on the stomach and duodenum mucosa or if you have had this disease in the past.
- If you are pregnant or breastfeeding.

**USE KLOORHEX PLUS CAREFULLY in the following situations**

- If you have kidney failure, heart failure or liver failure.
- If there is reversible discoloration on the tongue and teeth in the mouth (Teeth staining is harmless and can be minimized by brushing before application).

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

### **Using KLORHEX PLUS with food and drink**

KLORHEX PLUS has no interaction with food and drink due to the way of use.

### **Pregnancy**

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

Do not use KLORHEX PLUS if you are pregnant.

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

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication*

While using KLORHEX PLUS, breastfeeding should be discontinued or the drug should be discontinued.

### **Vehicle and machine use**

The effect of KLORHEX PLUS on the ability to drive and use machines has not been studied, but is not expected based on its pharmacodynamic properties and overall safety profile.

### **Important information about some of the ingredients of KLORHEX PLUS**

Although the product contains propylene glycol, sorbitol, glycerol and sodium, it does not require any warning due to the way of use and dosage.

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

Flurbiprofen, one of the active ingredients of KLORHEX PLUS, may rarely reduce the diuretic activity of furosemide. Also, flurbiprofen may rarely interact with anticoagulant drugs. In addition, flurbiprofen has no interaction with digoxin, tolbutamide and antacids.

The salts of chlorhexidine, one of the active ingredients of KLORHEX PLUS, are incompatible with soap and other negatively charged (anionic) compounds, chloramphenicol (antibiotic type), some inorganic salts and organic compounds.

*If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.*

### **3. How to use KLORHEX PLUS?**

#### **Instructions for proper use and dose/frequency of administration:**

It is applied directly to the affected area 3 times a day by making 3 sprays. Each spray is 0.13 ml and contains 0.325 mg of flurbiprofen and 0.156 mg of chlorhexidine.

#### **Application route and method:**

KLORHEX PLUS oral spray is applied by spraying to the relevant area in the mouth, it should not be swallowed.

#### **Different age groups:**

##### **Pediatric population:**

It should not be used in children under 12 years of age.

##### **Geriatric population:**

There are no data on its use in the elderly.

#### **Special use cases:**

##### **Kidney failure:**

It should be used with caution in patients with renal impairment.

##### **Liver failure:**

It should be used with caution in patients with hepatic impairment.

*If you have the impression that the effect of KLORHEX PLUS is too strong or too weak, talk to your doctor or pharmacist.*

#### **If you use more KLORHEX PLUS than you should:**

*If you have used more than you should use from KLORHEX PLUS, talk to a doctor or pharmacist.*

#### **If you forget to use KLORHEX PLUS:**

If you forget to take your medicine, wait and take your next dose on time.

Do not take a double dose to make up for forgotten doses.

#### **Effects that may occur when treatment with KLORHEX PLUS is terminated:**

There is no information on the effects that may occur when treatment with KLORHEX PLUS is terminated.

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

Like all medicines, there may be side effects in people who are sensitive to the ingredients of KLORHEX PLUS.

Side effects are classified as:

Very common: may occur in at least 1 in 10 patients.

Common: less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1,000 patients.

Rare: less than 1 in 1,000 patients, but more than 1 in 10,000 patients.

Very rare: less than 1 in 10,000 patients.

Unknown: Cannot be estimated from available data.

**If any of the following occur, stop using KLORHEX PLUS and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

**Common:**

- Change in taste
- Dişlerde ve diğer ağız içi yüzeylerde lekelenme

**Unknown:**

- Sensitivity findings
- Local irritations

*If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.*

#### **5. Storage of KLORHEX PLUS**

*Keep KLORHEX PLUS out of the sight and reach of children and in its package. 25°C altındaki oda sıcaklığında saklayınız.*

**Use in accordance with expiration dates.**

*Do not use KLORHEX PLUS after the expiry date on the package. Do not use KLORHEX PLUS if you notice any damage to the product and/or its packaging.*

Do not throw away expired or unused medicines! Environment and Urbanism

Give it to the collection system determined by the Ministry of Health.

**Marketing Authorization Holder:** Drog-san İlaçları San. ve Tic. A.Ş. Oğuzlar Mah. 1370. sok.  
7/3 Balgat-ANKARA

**Manufacturing Site:** Drog-san İlaçları San. ve Tic. A.Ş. Esenboğa Merkez Mah. Çubuk cad.  
No: 31 06760 Çubuk / Ankara

*This patient information leaflet was 19/07/2018.*