

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### SEPTOLETE lemon

1,2 mg pastilles

CETYLPYRIDINIUM

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*• 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.*

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*• 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 •*

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#### What is in this leaflet?

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

#### 1. WHAT SEPTOLETE IS AND WHAT IT IS USED FOR

SEPTOLETE lemon pastilles have local analgesic and anti-microbial effect.

Pastilles contain cetylpyridinium chloride, an antiseptic that destroys a range of bacteria and fungi, and to a certain extent impedes the development of the virus.

Pastilles disinfect the mouth and pharynx facilitating the pain and a feeling of discomfort associated with inflammation of the mouth and pharynx, and they prevent the development of severe bacterial infections.

Because of the good moisturizing ability and reduction of surface tension, cetylpyridinium chloride penetrates into parts of the lining of the mouth and throat that are hard to reach, and prevents the growth of bacteria.

Benzocaine is a local anesthetic, suitable for the relief of pain often associated with infection and inflammation in the mouth and pharynx.

Septolete lemon has a pleasant and refreshing taste of lemon.

Pastilles are recommended:

- For the local treatment of mild infections of the mouth and throat (pharyngitis, laryngitis, beginning of angina)
- For the inflammation of the gums (gingivitis) and the lining of the mouth (stomatitis)
- For cold and flu symptoms such as soreness, dryness and sore throat
- For hoarseness caused by colds and bad breath.

## 2. BEFORE YOU TAKE SEPTOLETE

### **Do not take SEPTOLETE**

- If you are allergic to cetylpyridinium, or other ingredients of this medicine

### **Take special care with SEPTOLETE**

- SEPTOLETE lemon is not recommended for children under 4 years.
- If you have open sores in the mouth, because cetylpyridinium chloride slows wound healing.
- If you have serious infection accompanied by high fever, headache and vomiting, be sure to check with your doctor, especially if your symptoms do not improve after 3 days.
- If you have diabetes, keep in mind that each pastille contains 1 g of maltitol. The effect of maltitol on the blood sugar level is low because of the slow hydrolysis and absorption in the digestive system.
- If you have a chronic cough and hoarseness, consult a doctor.

Consult your doctor even if some of the above related to you in the past.

Do not take higher doses than prescribed.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those that are not prescribed.

Septolete lemon has no effect on other medicines.

The use of surface active anions (eg, toothpaste) reduces the efficiency of cetylpyridinium chloride.

### **SEPTOLETE with food and drink**

Do not take SEPTOLETE lemon together with milk, because milk reduces the efficiency.

Do not take SEPTOLETE lemon before or during meals. Do not eat or drink for at least one hour after taking SEPTOLETE lemon.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Since there is no enough data on the safety during pregnancy and breastfeeding, the use of this medicine during pregnancy and lactation is not recommended.

### **Driving and using machines**

No specific precautions are required.

Important information about some of the ingredients of SEPTOLETE

Pastilles contain natural color, and the color of pastilles may fade over time if exposed to light, but it has no effect on their efficiency.

SEPTOLETE lemon pastilles contain maltitol and maltitol liquid. If your doctor told you that you have intolerance to certain sugars, consult your doctor before taking this medicine.

Pastilles contain sodium benzoate (E211), which can irritate the skin, eyes and mucous membranes.

## 3. HOW TO TAKE SEPTOLETE

Always take Septolete lemon as directed by your doctor. If you are not sure how to take your medicine you should contact your doctor or pharmacist.

Adults and children over 12 years

Dissolve 1 pastille in the mouth every 2 to 3 hours. The recommended daily dose is up to 8 pastilles.

Children aged 10-12 years

Dissolve 1 pastille in the mouth every 3 to 4 hours. The recommended dose is up to 6 pastilles daily.

Children from 4-10 years

Dissolve 1 pastille in the mouth every 3 to 4 hours. The recommended dose is up to 4 pastilles per day.

Pastilles SEPTOLETE lemon are not recommended for children under 4 years of age.

***Do not take SEPTOLETE lemon just before or during meals.***

Do not eat or drink for at least one hour after taking the medicine.

If you have the impression that the effect of Septolete lemon pastilles is too strong or too weak, talk to your doctor or pharmacist.

***If you take more SEPTOLETE than you should***

Considering the amount of active substances in each pastille, the risk of overdose is minimal. Taking a larger number of pastilles can cause digestive problems, nausea, vomiting and diarrhea. In this case, stop taking the medicine, drink plenty of water or milk and consult your doctor or pharmacist.

If you forget to take SEPTOLETE

Never double-up on a dose to make up for the one you have missed.

Talk to your doctor or pharmacist if you have any additional questions.

#### ***4. POSSIBLE SIDE EFFECTS***

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

- **Very common** (occurring in more than 1 in 10 patients);
- **common** (less than 1 in 10 patients)
- **uncommon** (less than 1 in 100 patients)
- **rare** (less than 1 in 1,000 patients)
- **very rare** (less than 1 in 10,000 patients)
- frequency not known.

**Rare:**

- Gastrointestinal problems, especially in susceptible persons and when using higher doses than those prescribed.

**Very rare:**

- Hypersensitivity reaction.

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

#### ***5. HOW TO STORE SEPTOLETE***

Keep out of reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Shelf life: 3 years.

Store below 25 °C.

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 SEPTOLETE contains**

The active substance is cetylpyridium chloride.

Each pastille contains 1.2 mg of cetylpyridium chloride (in the form of cetylpyridinium chloride monohydrate).

The other ingredients are liquid maltitol, maltitol (E965), mannitol (E421), levomenthol, essential lemon oil, glycerol (E422), virgin castor oil, colloidal anhydrous silica, magnesium stearate (E572), povidone, pharmaceutical waxes (beeswax (E901), carnauba wax (E903), shellac (E904)), titanium dioxide (E171), natural lime flavor, lemon flavor, orange flavor oil, natural yellow color (curcumin (E100)), water, arabic gum (E414), maltodextrin, citric acid (E330), citric acid esters of mono and diglycerides of fatty acids (E472c), sodium benzoate (E211) and potassium sorbate (E202).

### **What SEPTOLETE looks like and contents of the pack**

SEPTOLETE lemon pastilles are available in a box, with 18 pastilles in blister packs. One blister contains 9 pastilles.

Pastilles are yellow, round and slightly convex.

### **Supplier and Manufacturer**

#### **Regime of dispensing**

The medicine is issued without doctor's prescription.

#### **Manufacturer**

KRKA, d. d., Novo mesto

Šmarješka cesta 6, 8501 Novo mesto, Slovenia

#### **Manufacturer of the medicinal product**

KRKA, d. d., Novo mesto

Šmarješka cesta 6, 8501 Novo mesto, Slovenia