

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### Septolete plus

5 mg + 1 mg, pastilles

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

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

SEPTOLETE PLUS 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 PLUS pastilles are recommended for relieving the symptoms of pain, dryness and sore throat caused by:

- Mild infections of the mouth and throat (pharyngitis, laryngitis)
- Inflammation of the gums and oral mucosa (stomatitis, gingivitis), and
- Cold and flu.

## 2. BEFORE YOU TAKE SEPTOLETE PLUS

### **Do not take SEPTOLETE PLUS**

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

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

Tell your doctor if you:

- Septolete plus pastilles are not recommended for children under 6 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 lozenge 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.

### **Taking other medicines**

It is unknown if Septolete plus pastilles can affect the action of other medicines.

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

Do not take Septolete plus pastilles together with milk, because milk reduces their efficiency.

Do not take Septolete plus pastilles before or during meals. Do not eat or drink for at least one hour after taking Septolete plus pastilles.

### **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 PLUS

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

## 3. HOW TO TAKE SEPTOLETE PLUS

If you think that Septolete plus pastilles have too weak or too strong effect on you, you should contact a doctor.

### **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 6-12 years of age**

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

Pastilles Septolete plus pastilles are not recommended for children under 6 years of age.

Do not take Septolete plus pastilles just before or during meals.

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

### ***If you take more SEPTOLETE PLUS 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 PLUS

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) and **very rare** (less than 1 in 10,000 patients), frequency not known.

### **Rare:**

- Gastrointestinal problems such as nausea, vomiting and diarrhea.

### **Uncommon:**

- Hypersensitivity reactions, which may manifest as skin rash, itching, skin swelling, difficulty breathing, dizziness and low blood pressure.

Hypersensitivity reaction contact dermatitis occurs in less than 1% of patients. If you are allergic to benzocaine (also known as ester 4-aminobenzoic acid), there is a possibility that you are allergic to other local anesthetics of the same class, for example, procaine, tetracaine.

### ***Reporting of side effects***

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

By reporting side effects you can help provide more information on the safety of this medicine.

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

Keep out of the 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 PLUS contains***

The active substances are benzocaine and cetylpyridinium chloride. Each pastille contains 5 mg of benzocaine and 1 mg of cetylpyridinium chloride.

Other ingredients are essential peppermint oil, levomenthol, liquid maltitol, maltitol, mannitol, glycerol, virgin castor oil, magnesium stearate, anhydrous colloidal silica, povidone, pharmaceutically waxes (beeswax, carnauba wax, shellac), titanium dioxide (E171) and color blue V (E131).

***Regime of dispensing***

The medicine is issued without doctor`s prescription.

***Manufacturer***

KRKA, d. d., Novo mesto

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