

PACKAGE LEAFLET: INFORMATION FOR THE USER

SEPTOLETE

1 mg, pastilles

BENZALKONIUM

• 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.

• 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 •

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
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1. WHAT SEPTOLETE IS AND WHAT IT IS USED FOR

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

SEPTOLETE pastilles act directly on the causes of infection, prevent the spread of infection and effectively ease the symptoms of infection and inflammation of the mouth and throat.

SEPTOLETE pastilles are recommended for:

- Mild infections of the mouth and throat
- Inflammation of the gums and oral mucosa
- Cold and flu
- Hoarseness and bad breath.

2. BEFORE YOU TAKE SEPTOLETE

Do not take SEPTOLETE

- If you are allergic (hypersensitive) to benzalkonium chloride or any ingredient SEPTOLETE pastilles.

Take special care with SEPTOLETE

- SEPTOLETE is not recommended for children under 4 years.
- Do not use doses higher than prescribed.
- 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, you should know that each pastille contains 207.2 mg of lactose, 646.6 mg of sucrose, 33.67 mg of glucose and 152.7 mg of sorbitol.

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 has no effect on other medicines.

SEPTOLETE with food and drink

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

Do not take SEPTOLETE before or during meals.

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

SEPTOLETE pastilles contain lactose, glucose, sucrose and sorbitol. If your doctor told that you have intolerance to some sugars, before using this medicine, consult your doctor. Septolete pastilles can cause tooth decay in children.

3. HOW TO TAKE SEPTOLETE

Always take SEPTOLETE 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 are not recommended for children under 4 years of age.

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.

Very rare:

- Gastrointestinal problems, especially in susceptible persons and when using higher doses than those prescribed.
- 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 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: 2 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 ingredient is benzalkonium chloride.

1 pastille contains 1.0 mg of benzalkonium chloride.

Other ingredients in the core of pastilles are peppermint essential oil, eucalyptus essential oil, levomenthol, thymol, sucrose, liquid glucose, sorbitol, lactose, liquid paraffin, dimethylpolysiloxane, virgin castor oil, glycerol and magnesium stearate; in the coating of pastilles are quinoline yellow dye (E 104), indigo carmine (E132), titanium dioxide (E171), crospovidone, pharmaceutically waxes (beeswax, carnauba wax, shellac) sucrose.

What SEPTOLETE looks like and contents of the pack

Pastilles are available in boxes of 30 pastilles (2 x 15) in the blister.

Pastilles are green, round, smooth and biconvex.

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