

Package leaflet: Information for the user

Septotele plus honey & lime, 5 mg/1 mg lozenges

benzocaine/cetylpyridinium chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What Septotele plus honey & lime is and what it is used for
2. What you need to know before you take Septotele plus honey & lime
3. How to use Septotele plus honey & lime
4. Possible side effects
5. How to store Septotele plus honey & lime
6. Contents of the pack and other information

1. What Septotele plus honey & lime is and what it is used for

Septotele plus honey & lime lozenges have topical analgesic and antimicrobial effect. They disinfect the oral cavity and the pharynx and alleviate topical pain.

Lozenges contain antiseptic cetylpyridinium chloride that breaks down many bacteria and fungi and also inhibits the growth of viruses to certain extent. That way, it reduces inflammation in the oral cavity and the pharynx and primarily helps to prevent the development of more severe bacterial infections. As cetylpyridinium chloride is easily distributed and reduces surface tension, it also enters difficult to reach areas of the oral and pharyngeal mucosa and inhibits bacterial growth.

Benzocaine (active substance of Septotele plus honey & lime) is a topical analgesic suitable for alleviation of painful swallowing that frequently accompanies infections and inflammations of the oral cavity and the pharynx.

Septotele plus honey & lime lozenges contain polyols maltitol and mannitol. The medicine does not contain sugar that the bacteria need to grow. Septotele plus honey & lime lozenges are suitable for patients with diabetes, they do not cause dental caries and they have significantly better antiseptic effect due to sugar-free composition.

Septotele honey & lime lozenges are used as analgesic and disinfectant in inflammations of the oral cavity and the pharynx.

2. What you need to know before you take Septotele plus honey & lime

Do not use Septotele plus honey & lime

- If you are allergic to benzocaine, cetylpyridinium chloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Septotele plus honey & lime:

- if you have open wounds in the mouth, because cetylpyridinium chloride slows down healing of the wounds.
- if you have a severe infection involving high fever, headache and vomiting; contact your doctor, especially if symptoms do not improve within 3 days.
- if you have diabetes, you must keep in mind that each lozenge contains approximately 1 g of maltitol. Due to slow hydrolysis and absorption in the gastrointestinal system, maltitol has some effect on blood sugar level.

It is recommended not to exceed prescribed doses.

Children and adolescents

Septolete plus honey & lime lozenges are not recommended for children under 6 years of age.

Other medicines and Septolete plus honey & lime

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

Septolete plus honey & lime lozenges have no known effect on other medicines.

Septolete plus honey & lime with food and drink

Do not take Septolete plus honey & lime lozenges with milk, because milk reduces their efficacy. Do not take Septolete plus honey & lime lozenges before or during meals. Do not eat or drink for at least one hour after taking Septolete plus honey & lime lozenges.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Due to limited data on the safety of using the medicine in pregnant and breast-feeding women, it is not recommended to use Septolete plus honey & lime during pregnancy and breast-feeding.

Driving and using machines

Septolete plus honey & lime lozenges do not affect the ability to drive and use machines.

Septolete plus honey & lime contains maltitol and liquid maltitol.

If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine.

3. How to use Septolete plus honey & lime

Always use Septolete plus honey & lime exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose for adults is up to 8 lozenges a day. Dissolve one lozenge in your mouth in every 2-3 hours.

Use in children and adolescents

Recommended dose for children aged 12 years or older is up to 8 lozenges a day. Dissolve one lozenge in your mouth in every 2-3 hours.

Recommended dose for children aged 6-12 is up to 4 lozenges a day. Dissolve one lozenge in your mouth in every 4 hours.

If you take more Septolete plus honey & lime than you should

The possibility of overdose is minimal considering the amount of active substance in each lozenge. Swallowing large number of lozenges may cause gastrointestinal disorders, nausea, vomiting and

diarrhoea. In that case stop using the medicine, drink plenty of water or milk and talk to your doctor or pharmacist.

If you forget to take Septolete plus honey & lime

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

If you stop taking Septolete plus honey & lime

You may stop taking Septolete plus honey & lime as soon as you no longer need it.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Rare (may affect up to 1 in 1,000 people):

- gastrointestinal disorders

Very rare (may affect up to 1 in 10,000 people):

- hypersensitivity reaction.

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. You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Septolete plus honey & lime

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package, protected from light and humidity.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Septolete plus honey & lime contains

- The active substances are benzocaine and cetylpyridinium chloride. Every lozenge contains 5 mg of benzocaine and 1 mg of cetylpyridinium chloride.
- The other ingredients are lime flavouring (natural lime flavouring, maltodextrin, acacia (E414)), levomenthol, mannitol (E421), colloidal silica anhydrous, magnesium stearate (E572), maltitol (E965), titanium dioxide (E171), colouring quinoline yellow (E104), caramel colouring (E150a), allura red colouring AC (E129), povidone K25, honey flavouring, essential peppermint oil, liquid maltitol, glycerol (E422), castor oil and pharmaceutical waxes (beeswax (E901), carnauba wax (E903), shellac (E904)).

What Septolete plus honey & lime looks like and contents of the pack

Lozenges are dark yellow, round, smooth and biconvex.

Package contains 18 lozenges (2 blister packs, 9 lozenges in each).

Marketing Authorisation Holder and Manufacturer

KRKA, d. d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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