

Package leaflet: Information for the user

Septotele Lemon, 1.2 mg lozenges Cetylpyridinium chloride

Read all of this leaflet carefully before you start taking 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

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1. What Septotele Lemon is and what it is used for

Septotele Lemon lozenges have topical antimicrobial effect. They contain antiseptic cetylpyridinium chloride that breaks down bacteria and fungi and also inhibits the growth of viruses to certain extent. Lozenges disinfect the oral cavity and throat, thus alleviating the inflammation of the oral cavity and the pharynx.

Septotele Lemon is indicated for antiseptic treatment of bacterial and fungal inflammations of the oral cavity and pharynx.

Because of its good wetting and small surface tension, cetylpyridinium chloride also enters difficult to reach areas of the oral and pharyngeal mucosa and inhibits bacterial growth.

Septotele Lemon lozenges have pleasant and refreshing taste of lemon.

They do not contain sucrose that would facilitate bacterial growth and thus they do not cause tooth decay; antiseptic has much better effect in sugar-free base.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you use Septotele Lemon

Do not use Septotele Lemon:

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

Warnings and precautions

- if you have open wounds in the mouth (for example after tooth extraction, surgical removal of tonsils, etc.), because cetylpyridinium chloride may slow down healing of the wounds;
- if you have a severe infection involving high fever, headache and vomiting; contact your doctor, especially if your condition does 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

Not recommended for children under 4 years of age.

Other medicines and Septolete Lemon

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

There are no signs that Septolete Lemon lozenges affect other medicines.

Septolete Lemon with food and drink

Do not take Septolete Lemon together with milk because milk reduces their efficacy. Do not take Septolete Lemon before or during meals. Do not eat or drink for at least one hour after taking medicine.

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 it during pregnancy and breast-feeding.

Driving and using machines

There are no reports on the effect of Septolete Lemon lozenges on the ability to drive and use machines.

Septolete Lemon contains excipients

Lozenges contain natural colouring and thus their colour may fade over time if stored in a place exposed to light.

Septolete Lemon contains 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 take Septolete Lemon

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 12 years and older

Dissolve 1 lozenge in your mouth in every 2-3 hours, up to 8 lozenges a day.

Children from 10 to 12 years

Dissolve 1 lozenge in your mouth in every 3-4 hours, up to 6 lozenges a day.

Children from 4 to 10 years

Dissolve 1 lozenge in your mouth in every 3-4 hours, up to 4 lozenges a day.

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

If you feel that the effect of Septolete Lemon is too strong or too weak, talk to your doctor or pharmacist.

If you take more Septolete Lemon 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 Lemon

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

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, especially in sensitive people and at higher than prescribed doses.

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

- hypersensitivity reactions such as irritation and rash.

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 Lemon

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

Do not store above 25 °C.

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

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.

6. Contents of the pack and other information

What Septolete Lemon contains

- The active substance is cetylpyridinium chloride. One lozenge contains 1.2 mg of cetylpyridinium chloride.
- The other ingredients are: liquid maltitol, maltitol (E965), mannitol (E421), levomenthol, lemon oil, glycerol (E422), castor oil, colloidal anhydrous silica, magnesium stearate (E572), povidone, pharmaceutical waxes (beeswax (E901), carnauba wax (E903), shellac (E904)), titanium dioxide (E171), lime flavouring, lemon flavouring, orange oil flavouring, yellow colouring (curcumin (E100), water, acacia 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 Lemon looks like and contents of the pack

Lozenges are yellow, round and slightly biconvex.

Lozenges are available in cartons of 18 lozenges. Cartons contain 2 blister packs, 9 lozenges in each.

Marketing Authorisation Holder and Manufacturer

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

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