

Package leaflet: Information for the user

Septolete plus, 5 mg/1 mg lozenges

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

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

1. What Septolete plus is and what it is used for

Septolete plus 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 various bacteria and also inhibits the growth of viruses and fungi to certain extent. That way, it reduces inflammation in the oral cavity and the pharynx and 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 is a topical analgesic suitable for alleviation of painful swallowing that frequently accompanies infections and inflammations of the oral cavity and the pharynx.

Septolete plus lozenges contain polyols maltitol and mannitol. The medicine does not contain sugar that the bacteria need to grow. Septolete plus lozenges are suitable for patients with diabetes, they do not cause dental caries and they have significantly better antiseptic effect than preparations containing sugar.

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 Septolete plus

Do not take Septolete plus:

- if you are allergic to active substance(s) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Septolete plus.

Do not exceed recommended dose!

Note to patients with diabetes: One lozenge contains approximately 1 g of maltitol. Due to slow hydrolysis and absorption of maltitol in the gastrointestinal system, it has some effect on blood sugar level. Energetic value of maltitol (10 kJ/g or 2.4 kcal/g) is significantly lower than energetic value of sugar.

Children and adolescents

Septolete plus is not recommended for children under 6 years of age.

Septolete plus lozenges contain polyols. In large doses, polyols may cause diarrhoea, particularly in children.

Other medicines and Septolete plus

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

There have been no reports of interactions.

Septolete plus with food and drink

Do not take Septolete plus immediately prior to meal or with milk.

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.

Pregnant and breast-feeding women may use Septolete plus lozenges only when recommended by their doctor, if the potential benefits of the therapy outweigh the potential risk to the foetus/infant.

Driving and using machines

Septolete plus lozenges are not known to affect the ability to drive or use machines.

Septolete plus lozenges contain 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 take Septolete plus

Always take 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.

Recommended dose for adults and children aged 12 years and 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 years is up to 4 lozenges a day. Children at that age must dissolve one lozenge in every 4 hours.

If you take more Septolete plus than you should

In case of overdose consult your doctor or pharmacist.

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

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. Side effects occur very rarely, if Septolete plus lozenges are used as recommended. Using higher than recommended doses may cause gastrointestinal disorders in sensitive patients due to irritation of mucous membrane of the gastrointestinal tract. Allergic reactions may occur in people who are hypersensitive to any of the ingredients of the medicine.

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

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.

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 contains

- The active substances are benzocaine and cetylpyridinium chloride. One lozenge contains 5 mg of benzocaine and 1 mg of cetylpyridinium chloride.
- The other ingredients are: essential peppermint oil, levomenthol, liquid maltitol, maltitol, mannitol, glycerol, castor oil, magnesium stearate, colloidal anhydrous silica, povidone, pharmaceutical waxes, titanium dioxide (E171), blue colouring V (E131).

What Septolete plus looks like and contents of the pack

Blue, round, biconvex and glossy lozenges.

Lozenges are available in blister pack and carton of 18 or 30 lozenges.

Not all pack sizes may be marketed.

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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