

Package leaflet: Information for the user

Septolete omni eucalyptus 3 mg/1 mg lozenges benzydamine hydrochloride/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 have 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 Septolete omni eucalyptus is and what it is used for
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1. What Septolete omni eucalyptus is and what it is used for

Septolete omni eucalyptus lozenge is anti-inflammatory, analgesic and antiseptic medicine for local oral use. Septolete omni eucalyptus disinfect the mouth and throat and reduces signs of inflammation of throat such as pain, redness, swelling, heat and impaired function.

Septolete omni eucalyptus is used in the anti-inflammatory, analgesic and antiseptic treatment:

- of irritations in the throat, mouth and gums,
- in gingivitis and pharyngitis.

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 take Septolete omni eucalyptus

Do not take Septolete omni eucalyptus:

- if you are allergic to benzydamine hydrochloride, cetylpyridinium chloride or any of the other ingredients of this medicine (listed in section 6).
- this medicine should not be used in children aged under 6 years since pharmaceutical form is not suitable for this age group.

Warnings and precautions

Talk to your doctor or pharmacist before taking Septolete omni eucalyptus.

Do not use Septolete omni eucalyptus for more than 7 days. If the symptoms worsen or do not relieve after 3 days, or if other symptoms, such as fever, occur, consult a doctor.

The use of topical preparations, especially over a long period of time, may lead to sensitisation, in which case treatment must be discontinued.

Septolete omni eucalyptus must not be used in combination with anionic compounds, such as those present in toothpastes, therefore it is not recommended to use the product immediately before or after cleaning teeth.

Children and adolescents

Septolete omni eucalyptus must not be used in children under 6 years of age, since lozenge is not suitable for use in this age group.

Other medicines and Septolete omni eucalyptus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not use of other antiseptics when taking Septolete omni eucalyptus.

Septolete omni eucalyptus with food, drink and alcohol

Do not take Septolete omni eucalyptus together with milk because milk reduces their efficacy.

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

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.

Septolete omni eucalyptus is not recommended during pregnancy.

You should discuss breastfeeding with your doctor, and he/she will decide whether you should stop breast-feeding or stop the therapy with Septolete omni eucalyptus.

Driving and using machines

Septolete omni eucalyptus does not influence the ability to drive or use machines.

Septolete omni eucalyptus contains isomalt (E953)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Septolete omni eucalyptus

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

Adults

The recommended dosage is 3-4 lozenges a day. The lozenge should be slowly dissolved in the mouth every 3 to 6 hours.

Adolescents over 12 years of age

The recommended dosage is 3-4 lozenges a day. The lozenge should be slowly dissolved in the mouth every 3 to 6 hours.

Children from 6 to 12 years

The recommended dosage is 3 lozenges a day. The lozenge should be slowly dissolved in the mouth every 3 to 6 hours.

Children less than 6 years of age

Septolete omni eucalyptus must not be used in children aged less than 6 years.

Do not exceed the stated dose.

Do not take Septolete omni eucalyptus immediately before or during meals.

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

For optimal effect, it is not recommended to use the product immediately before or after cleaning teeth.

Duration of treatment

Do not use this medicine for more than 7 days. If the symptoms worsen or do not relieve after 3 days, or if other symptoms, such as fever, occur, consult a doctor.

Consult your doctor if the condition is recurrent or if you notice any recent changes in its characteristics.

If you take more Septolete omni eucalyptus than you should

In case of accidental ingestion of an excessive dose of this medicine, immediately tell your doctor or go to the nearest hospital.

If you forget to take Septolete omni eucalyptus

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):

- hives (urticarial), increase in the reactivity of the skin to sunlight (photosensitivity),
- sudden, uncontrolled narrowing of airways in lungs (bronchospasm).

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

- local irritation in the oral cavity, sensation of burning in the oral cavity.

Not known (frequency cannot be estimated from the available data):

- allergic reaction (hypersensitivity): serious allergic reaction (anaphylactic shock), signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, and which may be potentially life-threatening,
- burning of the oral mucosa, loss of sensation (anaesthesia) of the oral mucosa.

Usually these side effects are transitory. However, when they do appear, it is recommended to talk to your doctor or pharmacist. By following the instructions in the patient information leaflet you will reduce the risk of side effects.

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 the national reporting system listed in www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Septolete omni eucalyptus

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 packaging after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light.

This medicinal product does not require any special temperature storage conditions.

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 omni eucalyptus contains

- The active substances are benzydamine hydrochloride and cetylpyridinium chloride. Each lozenge contains 3 mg benzydamine hydrochloride and 1 mg cetylpyridinium chloride.
- The other ingredients are eucalyptus oil, levomenthol, citric acid (E330), sucralose (E955), isomalt (E953), brilliant blue FCF (E133). See section 2 “Septolete omni eucalyptus contains isomaltitol (E953)”.

What Septolete omni eucalyptus looks like and contents of the pack

Round, blue-white to blue lozenges with bevelled edges. Some small scratches could be present. Lozenge diameter: 18.0 mm – 19.0 mm, thickness: 7.0 mm – 8.0 mm.

Septolete omni eucalyptus is available in boxes of 8, 16, 24, 32 or 40 lozenges in blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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

Manufacturers

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8501 Novo mesto
Slovenia

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

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