

Package leaflet: Information for the user

Septolete omni lemon and elder flower 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.

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1. What Septolete omniSeptolete omni lemon and elder flower is and what it is used for

Septolete omniSeptolete omni lemon and elder flower contains the active substance benzydamine hydrochloride and cetylpyridinium chloride.

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

Septolete omniSeptolete omni lemon and elder flower is used for the treatment of symptoms of sore throat associated with mild infections in the mouth and throat (including 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 omniSeptolete omni lemon and elder flower

Do not take Septolete omni lemon and elder flower:

- if you are allergic to benzydamine hydrochloride, cetylpyridinium chloride or any of the other ingredients of this medicine (listed in section 6).
- this medicine must not be used in children aged under 6 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Septolete omni lemon and elder flower.

Do not use Septolete omni lemon and elder flower 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 the treatment must be discontinued and doctor consulted to set up a suitable therapy.

Septolete omni lemon and elder flower 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.

Take special care:

- If you are allergic to salicylates (e.g. acetylsalicylic acid and salicylic acid) or to other anti-inflammatory painkillers called non-steroidal anti-inflammatory drugs (NSAIDs). The use of this product is not advisable.
- If you have or have ever had a bronchial asthma. A caution should be exercised in this case.

Children and adolescents

Septotele omni lemon and elder flower must not be used in children under 6 years of age.

Other medicines and Septotele omni lemon and elder flower

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 Septotele omni lemon and elder flower.

Septotele omni lemon and elder flower with food, drink and alcohol

Do not take Septotele omni lemon and elder flower together with milk because milk reduces its efficacy.

Do not take Septotele omni lemon and elder flower before or during meals and drinking. Do not eat or drink for at least one hour after taking Septotele omni lemon and elder flower.

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.

Septotele omni lemon and elder flower 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 Septotele omni lemon and elder flower.

Driving and using machines

Septotele omni lemon and elder flower does not influence the ability to drive or use machines.

Septotele omni lemon and elder flower contains isomalt (E953), butylated hydroxyanisole (E320) and sodium benzoate (E211)

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

Butylated hydroxyanisole may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

This medicine contains up to 0,00075 mg sodium benzoate in one lozenge. Can cause local irritation.

3. How to take Septotele omni lemon and elder flower

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 of age

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 lemon and elder flower must not be used in children aged less than 6 years.

Do not exceed the stated dose.

Do not take Septolete omni lemon and elder flower immediately before or during meals and drinking. Do not eat or drink for at least one hour after taking the medicine. 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 lemon and elder flower 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 lemon and elder flower

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 (urticaria), 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 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 lemon and elder flower

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 “Kõlblik kuni”. 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 lemon and elder flower 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 peppermint oil, levomenthol, sucralose (E955), citric acid (E330), isomalt (E953), flavour citrus (containing butylated hydroxyanisole (E320)), flavour elder flower, curcumin (E100) (containing sodium benzoate (E211)), copper complexes of chlorophylls and chlorophyllins (E141). See section 2 "Septolete omni lemon and elder flower contains isomalt (E953), butylated hydroxyanisole (E320) and sodium benzoate (E211)".

What Septolete omni lemon and elder flower looks like and contents of the pack

Round lozenges with bevelled edges and rough surface from pale green to green colour. White patches, uneven colouring, presence of air bubbles in the “hard candy” mass and small jagged edges could be present. Lozenge diameter: 18.0 mm – 19.0 mm, thickness: 7.0 mm – 8.0 mm.

Septolete omni lemon and elder flower 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 manufacturer

Marketing Authorisation Holder:

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

Manufacturers

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

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

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