

## Package leaflet: Information for the user

### Septabene lemon and elderflower 3 mg/1 mg lozenges

benzylamine 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 Septabene lemon and elderflower is and what it is used for
2. What you need to know before you take Septabene lemon and elderflower
3. How to take Septabene lemon and elderflower
4. Possible side effects
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#### 1. What Septabene lemon and elderflower is and what it is used for

Septabene lemon and elderflower lozenge contains the active substance benzylamine hydrochloride and cetylpyridinium chloride.

Septabene lemon and elderflower lozenge is anti-inflammatory, analgesic (causing pain relief) and antiseptic (preventing the spread of pathogens) medicine for local oral use. Septabene lemon and elderflower disinfect the mouth and throat and reduces signs of inflammation of throat such as pain, redness, swelling, heat and difficulty swallowing.

Septabene lemon and elderflower is intended for the treatment of sore throat associated with mild infections in the mouth and throat (including inflammation of the pharynx) in adults, adolescents and children from 6 years of age.

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 Septabene lemon and elderflower

##### Do not take Septabene lemon and elderflower:

- if you are allergic to benzylamine 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 Septabene lemon and elderflower.

- 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 bronchial asthma. A caution should be exercised in this case.
- If you have open wounds or ulcerations in the mouth or throat.

Do not use Septabene lemon and elderflower for more than 7 days. If the symptoms worsen or do not

improve 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.

Septabene lemon and elderflower should 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**

Septabene lemon and elderflower must not be used in children under 6 years of age.

### **Other medicines and Septabene lemon and elderflower**

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

Do not use other antiseptics when taking Septabene lemon and elderflower.

### **Septabene lemon and elderflower with food and drink**

Do not take Septabene lemon and elderflower together with milk because milk reduces its efficacy.

### **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.

Septabene lemon and elderflower is not recommended during pregnancy.

Septabene lemon and elderflower should not be used during breast-feeding.

### **Driving and using machines**

Septabene lemon and elderflower does not influence the ability to drive or use machines.

### **Septabene lemon and elderflower contains isomalt (E 953), butylated hydroxyanisole (E 320), sodium benzoate (E 211) and sodium**

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 (E 211) in each lozenge. Sodium benzoate may cause local irritation.

This medicine contains less than 1 mmol sodium (23 mg) per lozenge, that is to say essentially 'sodium-free'.

## **3. How to take Septabene lemon and elderflower**

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*

Septabene lemon and elderflower must not be used in children aged less than 6 years.

**Do not exceed the stated dose.**

Do not take Septabene lemon and elderflower 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 improve 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 Septabene lemon and elderflower 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 Septabene lemon and elderflower**

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.

Uncommon (may affect up to 1 in 100 people):

- increase in the reactivity of the skin to sunlight (photosensitivity).

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

- hypersensitivity reaction,
- hives (urticaria),
- sudden, uncontrolled narrowing of airways in lungs (bronchospasm) or vocal cords (laryngospasm).

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):

- 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,
- discoloration of the tongue and teeth,
- reduced wound healing in mouth.

Usually these side effects are transitory. However, when they do appear, it is recommended to talk to your doctor or pharmacist.

**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 HPRAs Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Septabene lemon and elderflower

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 Septabene lemon and elderflower 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 (E 955), citric acid (E 330), isomalt (E 953), flavour citrus (containing butylated hydroxyanisole (E 320)), flavour elderflower, curcumin (E 100) (containing sodium benzoate (E 211)), copper complexes of chlorophyllins (E 141) (containing sodium). See section 2 "Septabene lemon and elderflower contains isomalt (E 953), butylated hydroxyanisole (E 320), sodium benzoate (E 211) and sodium".

### What Septabene lemon and elderflower 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.

Septabene lemon and elderflower 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

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

**This medicine is authorised in the Member States of the European Economic Area under the following names:**

Czech Republic	Neoseptolet combi citron a bezový květ
Ireland	Septabene lemon and elderflower
Germany	Septoflam Haltabletten

**This leaflet was last revised in**

Detailed information on this medicine is available on the HPRAs website ([www.hpra.ie](http://www.hpra.ie))