

1.3.1	Benzydamine hydrochloride + Cetylpyridinium chloride
SPC, Labeling and Package Leaflet	IE

Package leaflet: Information for the user

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

1. What Septabene is and what it is used for

Septabene lozenge contains the active substance benzydamine hydrochloride and cetylpyridinium chloride.

Septabene lozenge is anti-inflammatory, analgesic and antiseptic medicine for local oral use.

Septabene disinfect the mouth and throat and reduces signs of inflammation of throat such as pain, redness, swelling, heat and impaired function.

Septabene is used for the treatment of symptoms of sore throat associated with mild infections in the mouth and throat (including 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 Septabene

Do not take Septabene:

- 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 Septabene.

Do not use Septabene 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.

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Septabene 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.

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

Children and adolescents

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

Other medicines and Septabene

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.

Septabene with food, drink and alcohol

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

Do not take Septabene before or during meals and drinking. Do not eat or drink for at least one hour after taking Septabene.

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 is not recommended during pregnancy.

Septabene should not be used during breast-feeding.

Driving and using machines

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

Septabene 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 Septabene

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.

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

Do not exceed the stated dose.

Do not take Septabene 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 Septabene 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

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):

- severe allergic reaction (a so called anaphylactic reaction),
- 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

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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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Septabene

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.

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 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, anhydrous citric acid (E330), sucralose (E955), isomalt (E953), brilliant blue FCF (E133).

What Septabene 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.

Septabene 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 medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic	Benzydamin/Cetylpyridinium chlorid Krka
Ireland	Septabene
Germany	Septotele

This leaflet was last revised in