What is in this leaflet

1. What Septabene is and what it is used for

Septabene oromucosal spray, solution is an anti-inflammatory, analgesic and antiseptic medicine for local oral use. Oromucosal spray disinfects the mouth and throat and reduces signs of inflammation of throat such as pain, redness, swelling, heat and impaired function.

Septabene is used in the anti-inflammatory, analgesic and antiseptic treatment:
- of irritations in the throat, mouth and gums,
- in gingivitis, pharyngitis and laryngitis and
- before and after tooth extractions.

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 Septabene

Do not use 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 should not be used in children aged under 6 years
- since this pharmaceutical form is not suitable for this age group.

Warnings and precautions

Talk to your doctor or pharmacist before using 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 treatment must be discontinued.

Septabene 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.

Direct contact of Septabene oromucosal spray, solution with eyes should be avoided. The product must not be inhaled.

**Children and adolescents**
Septabene must not be used in children under 6 years of age, since oromucosal spray is not suitable for use in this age group.

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

**Driving and using machines**
Septabene does not influence the ability to drive or use machines.

**Septabene contains ethanol**
This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

**3. How to use Septabene**
Always use 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.

**Adults**
For a single dose, press the spray head **once to twice**. You may repeat this every 2 hours, 3-5 times daily.

**Use in children**
*Children over 12 years of age*
For a single dose, press the spray head **once to twice**. You may repeat this every 2 hours, 3-5 times daily.

*Children from 6 to 12 years of age*
For a single dose, press the spray head **once**. You may repeat this every 2 hours, 3-5 times daily.

Septabene should not be used in children aged under 6 years.
1.3.1 Benzydamine hydrochloride + Cetylpyridinium chloride

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

Method of administration
Before the first use of Septabene oromucosal spray, press the spray head several times in order to obtain even delivery. If the spray has not been used for a long period of time (like at least for one week), press the spray head one time in order to obtain even delivery.

Remove the plastic cap before use.

Open your mouth wide, point the spray nozzle towards your throat and press the spray head 1-2 times. Hold your breath while spraying.

When the spray head is pressed once, 0.1 ml of oromucosal spray, solution, which contains 0.15 mg benzydamine hydrochloride and 0.5 mg cetylpyridinium chloride is released.

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 use 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 use 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.

Rare (may affect up to 1 in 1,000 people):
- hypersensitivity reaction,
1.3.1  Benzydamine hydrochloride + Cetylpyridinium chloride  

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oromucosal spray 1.5 + 5.0 mg + mg_ml

- 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, mild sensation of burning in the oral cavity.

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

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://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.

Do not store above 25°C.

After first opening of the container, the product should be used within 6 months when stored at temperature below 25°C.

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 ml of oromucosal spray, solution contains 1.5 mg benzydamine hydrochloride and 5 mg cetylpyridinium chloride.
  One spray contains 0.1 ml of oromucosal spray, solution, containing 0.15 mg benzydamine
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oromucosal spray 1.5 + 5.0 mg + mg_ml

- hydrochloride and 0.5 mg cetylpyridinium chloride.
- The other ingredients are ethanol (96 per cent), glycerol (E422), macrogolglycerol hydroxystearate, saccharin sodium (E954), peppermint oil, purified water.

What Septabene looks like and contents of the pack

Oromucosal spray, solution (oromucosal spray) is clear, colourless to yellowish liquid.

Septabene is available in boxes of 30 ml of oromucosal spray, solution, in a plastic spray container with spray pump and cap. 30 ml of oromucosal spray, solution is sufficient for 250 sprays.

Marketing Authorisation Holder

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

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:

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<th>Name of the medicinal product</th>
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This leaflet was last revised in