

1.3.1	Benzydamine hydrochloride + Cetylpyridinium chloride	IE
SPC, Labeling and Package Leaflet	oromucosal spray 1.5 + 5.0 mg + mg_ml	

Package leaflet: Information for the user

Septabene 1.5 mg/ml + 5.0 mg/ml oromucosal spray, solution benzydamine hydrochloride/cetylpyridinium chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use 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 use Septabene
3. How to use 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 oromucosal spray, solution is 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 and pharyngitis 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.

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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, macroglycerol hydroxystearate and sodium

This medicine contains 267.60 mg of alcohol (ethanol) in 1 ml of oromucosal spray, solution. The amount in 1 ml of this medicine is equivalent to less than 7 ml beer or 3 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

Macroglycerol hydroxystearate may stomach upset and diarrhea.

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

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 and adolescents

Adolescents 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.

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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.

Do not use Septabene in children aged under 6 years.

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

If you take too much or you accidentally swallow large quantities of your medicine, contact immediately your doctor or pharmacist for advice.

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

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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:

HPRA Pharmacovigilance

Website: www.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 12 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

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cetylpyridinium chloride.

One actuation contains 0.1 ml of oromucosal spray, solution, containing 0.15 mg benzydamine hydrochloride and 0.5 mg cetylpyridinium chloride.

- The other ingredients are ethanol (96 per cent), glycerol (E422), macroglycerol hydroxystearate, saccharin sodium (E954), peppermint oil, purified water. See section 2 “Septabene contains ethanol, macroglycerol hydroxystearate and sodium”.

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 actuations.

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:

Name of the Member State	Name of the medicinal product
Czech Republic, Ireland, Lithuania, Latvia, Slovenia	Septabene
Bulgaria	Septolete total (Септолете тотал)
Estonia, Romania	Septolete omni
Slovak Republic, Hungary	Septolete extra
Poland	Septolete ultra
Portugal	Septolete Duo Spray
Croatia	Septolete duo
Italy	Septafar

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