Package leaflet:

Information for the user

Benzydamine Hydrochloride 0.15%w/v Oromucosal Spray

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

- This medicine is available without prescription. 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.
- If you have any further questions, ask your doctor or pharmacist.
- 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 contact a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

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

1. What Benzydamine Spray is and what it is used for

The name of your medicine is Benzydamine 0.15%w/v Oromucosal Spray (hereafter referred to as Benzydamine Spray in this leaflet).
Benzydamine Spray contains the active ingredient benzydamine hydrochloride, which belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).
Benzydamine Spray works by stopping pain and swelling (inflammation). It is used to treat many painful conditions of the mouth or throat including:

- Mouth ulcers
- Sore mouth or gums
- Sore throat
- Discomfort associated with dentures or dental work

2. What you need to know before you use Benzydamine Spray

Do not use Benzydamine Spray:

- if you are allergic to benzydamine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, dentist or pharmacist before using Benzydamine Spray:

- if you have a history of asthma
- if you are allergic to aspirin or other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

Other medicines and Benzydamine Spray
Tell your doctor, dentist or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.
Pregnancy and breast-feeding
Pregnancy
You should not use Benzydamine Spray during pregnancy unless absolutely necessary and advised by your doctor. If you need treatment the lowest dose for the shortest time possible should be used.
If you need treatment during the **first 6 months of pregnancy** or while **you are trying to get pregnant**, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Benzydamine Spray can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby.
If you need treatment for longer than a few days, your doctor may recommend additional monitoring.
Do not take this medicine if you are in the **last 3 months of pregnancy** as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.
Breast-feeding
It is not known Benzydamine Spray is excreted into breast milk. Therefore, Benzydamine Spray should not be used during breastfeeding unless absolutely necessary and advised by your doctor.
Benzydamine Spray contains:
This medicine contains less than 1 mmol sodium (23 mg) per dose of 8 puffs, that is to say essentially 'sodium-free'.
This medicine contains glycerol which may cause headache, stomach upset and diarrhoea.
This medicine contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
This medicine contains only a small amount of ethanol (alcohol), less than 100mg per dose.

3. How to use Benzydamine Spray

Always use Benzydamine Spray exactly as your doctor, dentist or pharmacist has told you. Check with your doctor, dentist or pharmacist if you are not sure.
Do not use Benzydamine Spray in or near your eyes. If any spray gets into your eyes, wash them **immediately** with cold water.
How much Benzydamine Spray to use:

- **Adults, the elderly and children over 12 years:** 4 to 8 sprays to the sore area every 1½-3 hours
- **Children (6-12 years):** 4 sprays to the sore area every 1½-3 hours
- **Children under 6 years:** 1 spray for each 4kg of bodyweight, to a maximum of 4 sprays, to the sore area every 1½-3 hours

Contact your doctor, dentist or pharmacist if your symptoms worsen or they do not improve.
How to use the spray

1. Fit the extension arm to the pump spray before use.
2. To use the spray, hold the bottle in an upright position.
3. The first time you use the spray, you need to prime it. Point the spray arm away from your face.

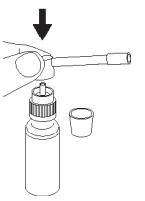


Figure 1

Pharmacode
Pharmacode

Press down firmly on the plunger until a fine spray appears from the end of the spray arm (figure 2).

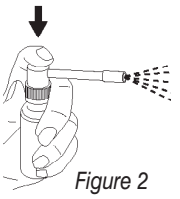


Figure 2

The spray is now ready to use.

4. Aim the spray arm at the sore part of your mouth or throat and press down on the plunger again.

One press releases one spray of medicine.

5. After spraying the correct number of sprays, wipe the end of the spray arm with a tissue. This helps to stop it becoming blocked.
6. Do not push anything into the end of the spray arm. If it becomes blocked, return the spray to your pharmacist.

If you use more Benzydamine Spray than you should

If you use too much or you accidentally swallow large quantities of Benzydamine Spray, contact your doctor, dentist or pharmacist immediately for advice. Remember to take this leaflet with you.

If you forget to use Benzydamine Spray

Take it as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do not use 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, dentist or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, seek medical advice immediately:

- 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

Other side effects - if any get serious, tell your doctor

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

- Numbness and/or stinging in the mouth. The stinging has been reported to disappear upon continuation of treatment, however if it persists, treatment may need to be discontinued

Very rare side effects (may affect less than 1 in 10,000 people):

- Closing up of the throat (laryngospasm)
- Difficulty breathing and wheezing (bronchospasm)
- Severe itching (pruritus)
- Skin rashes with the formation of wheals (urticaria)
- Abnormal sensitivity of the skin to sunlight (photosensitivity)
- Skin rash

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

- Swelling of the deeper layers of the skin caused by a build-up of fluid (angioedema)
- Allergic reaction (hypersensitivity)

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Benzydamine Spray

- 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 bottle and carton after EXP. The expiry date refers to the last day of that month. Discard the opened spray 12 months after first using.
- Store in an upright position.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment

6. Contents of the pack and other information

What Benzydamine Spray contains

The active ingredient is benzydamine hydrochloride at a concentration of 0.15%w/v. Each spray contains 255 micrograms of benzydamine hydrochloride.

The other ingredients are: glycerol, ethanol 96%, methyl parahydroxybenzoate (E218), saccharin sodium (E954), sodium hydrogen carbonate, polysorbate 20, mint flavour (maltodextrin and menthol) and purified water.

What Benzydamine Spray looks like and contents of the pack

Benzydamine Spray is a clear, colourless liquid, with a mint odour. It is available in a multidose spray bottle fitted with a metering pump. This means it provides a measured amount of spray each time it is used.

Each 15 ml bottle contains approximately 85 actuations.

Each 30 ml bottle contains approximately 170 actuations.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Tillomed Laboratories Limited, 220 Butterfield
Great Marlings, Luton, LU2 8DL, United Kingdom

Manufacturers

Tillomed Laboratories Limited, 220 Butterfield
Great Marlings, Luton, LU2 8DL, United Kingdom
Tillomed Malta Limited, Malta Life Sciences Park
LS2.01.06 Industrial Estate, San Gwann
SGN 3000, Malta

Other formats

To get this information in large print or another format, please email medical.information@tillomed.com or call 0800 970 6115.

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