

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.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- This medicine is available without prescription. However, you still need to use it carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

The name of this medicine is Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray (called Benzydamine Hydrochloride throughout this leaflet).

It contains the active substance benzydamine hydrochloride, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

Benzydamine Hydrochloride works by stopping pain and swelling (inflammation). It is used to treat many painful conditions of the mouth or throat including:

- Mouth ulcers
- Teething
- Sore throat
- Sore tongue or gums
- Discomfort associated with dentures or dental work.

2. What you need to know before you take Benzydamine Hydrochloride

Do not use Benzydamine Hydrochloride if you are:

- allergic to benzydamine hydrochloride
- allergic to any of the other ingredients in Benzydamine Hydrochloride (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Benzydamine Hydrochloride if you:

- have a history of asthma
- are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

If any of these apply, talk to your doctor or pharmacist.

Other medicines and Benzydamine Hydrochloride

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

Pregnancy, breast-feeding and fertility

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.

Do not take benzydamine hydrochloride 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. You should not take benzydamine hydrochloride during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period 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 hydrochloride 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.

Driving and using machines

Benzydamine Hydrochloride does not affect the ability to drive or to operate machines.

Benzydamine Hydrochloride contains methyl parahydroxybenzoate, ethanol and sodium

Each puff (0.18 ml) of the spray delivers 0.18 mg of methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

Each puff (0.18 ml) of the spray delivers 14.58 mg of ethanol 96%. The amount in one puff of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) in each puff (0.18ml), that is to say essentially 'sodium-free'.

3. How to use Benzydamine Hydrochloride

Important:

Always use Benzydamine Hydrochloride exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Do not use Benzydamine Hydrochloride in or near your eyes. If any spray gets in your eyes, wash them immediately with cold water.

How much Benzydamine Hydrochloride to use

- **Adults adolescents and elderly** – spray 4 - 8 puffs to the sore area every 1.5 - 3 hours.
- **Children 6 to 12 years of age** - spray 4 puffs to the sore area every 1.5 - 3 hours.
- **Children less than 6 years of age** - spray 1 puff for every 4 kilograms of body weight, up to a maximum of 4 puffs, to the sore area every 1.5 - 3 hours.

Contact your doctor if your symptoms worsen or they do not improve.

How to use the spray

1. Hold the bottle in an upright position.
2. You need to prime the spray the first time you use it (max. 5 sprays). Point the spray-tube away from your face. Press down firmly until a fine spray appears from the end of the spray-tube.
3. Aim the spray-tube at the affected area and press down. One press releases one actuation.
4. After spraying the desired number of actuations, wipe the end of the spray-tube with a tissue. This prevents the spray-tube becoming blocked.
5. Do not push anything into the end of spray-tube if it becomes blocked. Return the spray to your pharmacist.

If you use more Benzydamine Hydrochloride 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 Benzydamine Hydrochloride

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Benzydamine Hydrochloride can cause side effects, although not everybody gets them.

Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

- 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 include the following, if they get serious, please tell your doctor:

Uncommon (affects 1 in 1,000 people):

- Numbness and/or stinging in the mouth and/or throat.

Very rare (affects less than 1 in 10,000 people):

- Difficulty breathing and wheezing.
- Itching.
- Skin rash.

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

- Skin redness or swelling.
- Allergic reaction (Hypersensitivity).

Some people may react after using the product with a severe allergic reaction experiencing symptoms as described above (a so-called anaphylactic reaction) which may be potentially life-threatening. In this case you should seek immediate medical assistance.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 Hydrochloride

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 label and bottle after EXP. The expiry date refers to the last day of that month.

This medical product does not require any special storage condition.

Do not freeze. Store in an upright position. Once opened use within 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Benzydamine Hydrochloride contains

- The active substance is benzydamine hydrochloride at a concentration of 0.15% w/v.
- Each metered dose pump spray delivers benzydamine hydrochloride 0.15 % w/v, approximately 180 microlitres per puff.

- The other excipients are: sodium bicarbonate, polysorbate 20, ethanol 96%, glycerol, saccharin sodium, methyl parahydroxybenzoate (E218), peppermint oil and purified water.

What Benzydamine Hydrochloride looks like and contents of the pack

It is a mouth spray. It is a clear, colourless solution with mint odor that comes in an amber glass bottle fitted with a metered dose pump and a stopper-lid on the neck of sprayer. This means it provides a measured amount of spray each time it is used. Each bottle contains 30 ml of liquid and comes in a carton.

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This leaflet was last revised in September 2025