Package leaflet: Information for the user

Benzydamine 0.15% w/v Oromucosal Spray
benzydamine hydrochloride

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 has 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 7 days.

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

Benzydamine Spray is used for treating pain and inflammation (redness, swelling and a feeling of heat) in the throat or mouth. Benzydamine Spray contains benzydamine hydrochloride, one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

What this medicine does
Benzydamine Spray is used to treat many painful conditions affecting the throat or mouth including:
- Sore throat
- Sore tongue or gums
- Mouth ulcers
- Discomfort caused by dentures
- Pain after dental surgery

Benzydamine Spray works in the throat or mouth to help stop pain and inflammation (redness, swelling and a feeling of heat). It does this by stopping the formation of prostaglandins.
Prostaglandins are natural substances made by the body when it is injured or has an infection. They cause an increase in the blood supply to the area of injury or infection. This results in pain, redness, swelling and a feeling of heat in that area. Stopping the formation of prostaglandins reduces these effects.

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

Do not use Benzydamine Spray
If you are allergic to benzydamine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Benzydamine Spray
- If you have a history of asthma
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

Do not use this spray near your eyes. If you get it in your eyes accidentally, wash them **immediately** with cold water.

Other medicines and Benzydamine Spray
Tell your doctor or pharmacist if you are using, have recently used or might use 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.

You should not use Benzydamine Spray during pregnancy unless clearly necessary and advised by your doctor. If you need treatment the lowest dose for the shortest time possible should be used.

Driving and using machines
Benzydamine Spray has negligible influence on the ability to drive and use machines.

Benzydamine Spray contains methyl parahydroxybenzoate, ethanol and propylene glycol
Some of the non-active ingredients in your medicine may cause side effects:
- Methyl parahydroxybenzoate - this may cause allergic reactions (possibly delayed)
- Propylene glycol – this may cause skin irritation
- Ethanol-
  This medicinal product contains 0.0175 ml ethanol (96%) per 0.175 ml of Spray, equivalent to 351 µl (0.351ml) of beer, 140 µl (0.140ml) of wine per dose of 1 spray. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to use Benzydamine Spray

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.

Benzydamine Spray is for use in the throat or mouth. It should be sprayed onto the sore area of the mouth or throat according to the following instructions:

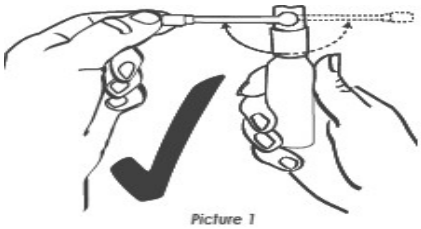
The recommended dose is:
Adults including the elderly
- Use 4 to 8 sprays every 1½ to 3 hours.

Use in children and adolescents
Children aged 6 to 12 years
- Use 4 sprays every 1½ to 3 hours.
- Children over 12 should use the adult dose.

Children under 6 years of age
- The dose is based on how much the child weighs.

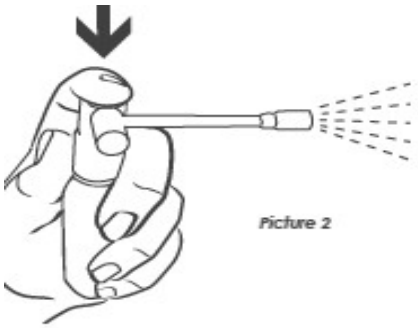
Do not use more than 4 sprays at any one time.
- Use one spray for each 4 kilograms that the child weighs but **do not use more than 4 sprays at any one time.**
- This dose should be used every 1½ to 3 hours.

How to use the spray
1. Always use the spray in the upright position.
2. Turn the spray arm, in either direction, until it is at right angles (90 degrees) to the body of the spray container as shown in picture 1. **Do not use the spray arm in any other position,** as the medicine may not come out properly.



Picture 1

3. The first time you use the spray, point the spray arm away from you and anyone else. Then press the white plunger down firmly several times until a fine spray appears out of the end of the spray arm as shown in picture 2. Your spray is now ready to use.



Picture 2

4. Point the spray arm at the sore part of your throat or mouth and press the white plunger down firmly. One press releases one spray of medicine.
5. Apply the correct number of sprays according to the instructions above. Then wipe the end of the spray arm with a clean tissue. This helps to prevent your spray blocking.
6. Turn the spray arm down into the closed position as shown in picture 3. This stops any more sprays of your medicine being released accidentally.

Picture 3

7. If your spray blocks or stops working properly, return it to your pharmacist. Do not push anything into the end of the spray arm to try to clear a blockage.

If you use more Benzydamine Spray than you should
If you use too many sprays of Benzydamine Spray, contact your doctor or pharmacist for advice.

If you forget to use Benzydamine Spray
- If you forget to use your spray, do not worry. Apply the correct number of sprays as soon as you remember and then carry on using the spray every 1½ to 3 hours as before.
- Do not use double the amount of sprays 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.

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, red and lumpy skin rash, swelling of

the face, mouth, lips, tongue, eyelids and /or throat, unexplained high temperature (fever) and feeling faint. and which may be potentially life-threatening. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

Other side effects:
Uncommon: may affect up to 1 in 100 people
- A feeling of numbness in your mouth
- A stinging feeling in your mouth:
  - this stinging usually disappears as you continue to use the spray
  - if the stinging does not go away stop using the spray and talk to your doctor or pharmacist

Very rare may affect up to 1 in 10,000 people
- Your skin becoming more sensitive to sunlight than normal causing an itchy, red, scaly rash, sometimes with blisters.

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 carton and the base of the can. The expiry date refers to the last day of that month.

Do not store above 25ºC. Keep the spray in the outer carton.

Once you have started using the spray, do not keep it for more than 6 months.

Do not use this medicine if you notice any damage to the spray container or spray arm. Return it to your pharmacist.
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 Benzydamine Spray contains
- The active substance is benzydamine hydrochloride. Each spray from the spray arm contains 262.5 micrograms of benzydamine hydrochloride.
- The other ingredients are glycerol, polysorbate 20, saccharin sodium, ethanol 96%, methyl parahydroxybenzoate, aniseed flavour (contains ethanol 95%), peppermint flavour (contains propylene glycol), water. (See section 2, Benzydamine Spray contains methyl parahydroxybenzoate and propylene glycol.)

What Benzydamine Spray looks like and contents of the pack
Benzydamine Spray is an oromucosal spray (a spray for use in the throat or mouth). It is a clear solution with a smell of peppermint. It is contained in a spray container fitted with a metering pump (a pump that delivers a measured amount of medicine) and nozzle (spray arm).
Each spray container holds 30ml of medicine.

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This leaflet was last revised in September 2025