

**Package leaflet: Information for the user**

**Benzylamine Hydrochloride 0.30 % w/v Oromucosal Spray**

benzylamine  
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, pharmacist or nurse have told you.  
- 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 benzylamine hydrochloride 0.30% w/v oromucosal spray is and what it is used for
2. What you need to know before you use benzylamine hydrochloride 0.30% w/v oromucosal spray
3. How to use benzylamine hydrochloride 0.30% w/v oromucosal spray
4. Possible side effects
5. How to store benzylamine hydrochloride 0.30% w/v oromucosal spray
6. Contents of the pack and other information

**1. What benzylamine hydrochloride 0.30% w/v oromucosal spray is and what it is used for**

Benzylamine hydrochloride 0.30% w/v oromucosal spray contains the active substance benzylamine hydrochloride, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

Benzylamine hydrochloride 0.30% w/v oromucosal spray works by stopping pain and swelling (inflammation). It is used to treat many painful conditions of the mouth or throat including:  
- Sore throat  
- Sore tongue or gums  
- After operations, at Laryngitis and in case of damage after radiotherapy

**2. What you need to know before you take benzylamine hydrochloride 0.30% w/v oromucosal spray**

**Do not use benzylamine hydrochloride 0.30% w/v oromucosal spray if:**

- You are allergic to benzylamine hydrochloride
- You are allergic to any of the other ingredients in benzylamine hydrochloride 0.30% w/v Oromucosal Spray (listed in section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using benzylamine hydrochloride 0.30% w/v oromucosal spray:  
• If you have a history of asthma  
• If you are allergic to acetylsalicylic acid or

other non-steroidal anti-inflammatory anti-inflammatory (NSAID) drugs

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

**Other medicines and benzylamine hydrochloride 0.30% w/v oromucosal spray**

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.

**Driving and using machines**

Benzylamine hydrochloride 0.30% w/v oromucosal spray does not affect the ability to drive or to operate machines.

**Benzylamine hydrochloride 0.30% w/v oromucosal spray Contains:**

This medicine contains methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed). This medicinal product contains benzyl alcohol. Benzyl alcohol may cause mild local irritation.

**3. How to use benzylamine hydrochloride 0.30% w/v oromucosal spray Important:**

Always use benzylamine hydrochloride 0.30% w/v oromucosal spray exactly as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Do not use benzylamine hydrochloride 0.30% w/v oromucosal spray in or near your eyes. If any spray gets in your eyes, wash them immediately with cold water.

Recommended treatment period is 5-7 days.

**How much benzylamine hydrochloride 0.30% w/v oromucosal spray to use**

- **Adults adolescents and elderly** – spray 2 - 4 puffs to the sore area every 1.5 – 3 hours.
- **Children 6 to 12 years of age** - spray 2 puffs to the sore area every 1.5 – 3 hours.
- **Children less than 6 years of age** - spray 1 puff for every 8 kilograms of body weight, up to a maximum of 2 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. Remove the protective cap
3. 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.
4. Aim the spray-tube at the affected area and press down. One press releases one actuation.
5. After spraying the desired number of actuations, wipe the end of the spray-tube with a tissue. This prevents the spray-tube becoming blocked.

6. Replace the protective cap after use. This prevents the actuation being accidentally released.

**If you use more benzylamine hydrochloride 0.30% w/v oromucosal spray than you should**

It should not cause you any problems if you accidentally take too much or you swallow some of your medicine. If you have any concerns, contact your doctor or pharmacist.

**If you forget to use benzylamine hydrochloride 0.30% w/v oromucosal spray**

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 about the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, benzylamine hydrochloride 0.30% w/v oromucosal spray 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:**

- severe allergic reaction (anaphylaxis) seen as swelling of throat and mouth, difficulty in swallowing or speaking, alterations in heart rate, severe asthma, collapse and unconsciousness

**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

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**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store benzylamine hydrochloride 0.30% w/v oromucosal 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 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.

Shelf life after first opening of the medicinal product: 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 Benzylamine Hydrochloride 0.30% w/v Oromucosal Spray contains**

The active substance is benzylamine hydrochloride at a concentration of 0.30% w/v.

Each metered dose pump spray delivers benzylamine hydrochloride 0.30 % w/v, approximately 0.18 ml per puff.

The other excipients are ethanol 96%, glycerol, polysorbate 80, saccharin sodium, methyl parahydroxybenzoate (E218), spearmint flavor 'containing benzyl alcohol', sodium hydrogen carbonate and/or hydrochloric acid for pH adjustment and purified water.

**What benzylamine hydrochloride 0.30% w/v oromucosal spray looks like and contents of the pack**

It is a mouth spray. It is a clear, colourless solution that comes in an amber glass bottle fitted with a spray 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 15 ml of liquid and comes in a carton.

**Marketing Authorisation Holder**

ABDI FARMA, Unipessoal Lda Quinta da Fonte, Rua dos Malhões, Edifício D. Pedro I 2770-071 Paço de Arcos, Portugal

**This medicinal product is authorised in the Member States of the EEA under the following names:**

UK and Ireland: benzylamine hydrochloride 0.30% w/v oromucosal spray

**Manufacturer**

HBM Pharma s.r.o. Sklabinska 30, 036 80 Martin Slovakia

Interpharma Services Ltd. 43A Cherni Vrach Blvd. Sofia 1407 Bulgaria

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