

Package leaflet: Information for the user

Benzydamine Hydrochloride 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, pharmacist or nurse have told you.

- This medicine is available with 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 0.15% w/v Oromucosal Spray is and what it is used for
2. What you need to know before you use Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray
3. How to use Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray
4. Possible side effects
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1. What Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray is and what it is used for

Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray contains the active substance benzydamine hydrochloride, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS.

Benzydamine Hydrochloride 0.15% 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:

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

2. What you need to know before you take Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray

Do not use Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray if:

- You are allergic to benzydamine hydrochloride
- You are allergic to any of the other ingredients in Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Benzydamine Hydrochloride 0.15% 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 Benzydamine Hydrochloride 0.15% 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

Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray does not affect the ability to drive or to operate machines.

Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray Contains:

This medicine contains glycerol which may cause headache, stomach upset and diarrhoea.

This medicine contains methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

Each puff (0.18 ml) of the spray delivers 0.18 milligrams of methyl parahydroxybenzoate and 14.58 milligrams of ethanol 96%.

3. How to use Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray

Important:

Always use Benzydamine Hydrochloride 0.15% 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 Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray in or near your eyes. If any spray gets in your eyes, wash them immediately with cold water.

Do not use Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray for more than 7 days except under medical supervision.

How much Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray 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 0.15% 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 Benzydamine Hydrochloride 0.15% 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, Benzydamine Hydrochloride 0.15% 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray

Do not use this medicine after the expiry date on the bottle. 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.

Keep this medicine out of the sight and reach of children.

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 Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray contains

The active substance is benzyamine 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 water, purified.

What Benzydamine Hydrochloride 0.15% 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 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.

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: Benzydamine Hydrochloride 0.15% w/v Oromucosal Spray

Manufacturer

HBM Pharma s.r.o.
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036 80 Martin
Slovakia

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