

Package leaflet: Information for the user

Orosoothe 0.15% w/v Oromucosal Spray

benzydamine hydrochloride

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

This medicine is available without prescription. However, you still need to use it carefully to get the best results from it. 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.
- Ask your pharmacist or doctor 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 or pharmacist if you do not feel better or your symptoms worsen after 7 days.

What is in this leaflet:

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

1. WHAT BENZYLAMINE IS AND WHAT IT IS USED FOR

Orosoothe Spray belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

Orosoothe Spray works by stopping pain and swelling (inflammation). It is used to treat painful conditions affecting the throat or mouth including:

- Sore throat
- Sore tongue or gums
- Mouth ulcers
- Discomfort caused by dentures or after dental work

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OROSOOTHE SPRAY

Do not use Orosoothe Spray

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

Take special care with Orosoothe Spray

Talk to your doctor or pharmacist before using Orosoothe Spray:

- If you have a history of Asthma.
- If you are allergic to acetylsalicylic acid or to other anti-inflammatory painkillers called NSAIDs.

Important information about some of the ingredients of Orosoothe Spray

- Orosoothe Spray contains methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

- This medicine contains 8.5mg of alcohol (ethanol) in each puff. The amount in 1 puff of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Other medicines and Orosoothe Spray

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

Pregnancy and breastfeeding

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 using Orosoothe Spray.

3. HOW TO USE OROSOOTHE SPRAY

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist told you. Check with your doctor or pharmacist if you are not sure.

Avoid contact with your eyes. If any spray gets in your eyes, wash them immediately with cold water.

How much Orosoothe Spray to take

Orosoothe Spray should be sprayed onto the sore area of the mouth or throat according to the following recommended dosage:

Adults including the elderly (and children over 12 years): Spray 4 to 8 puffs every 1½ to 3 hours.

Children aged 6 to 12 years: Spray 4 puffs every 1½ to 3 hours.

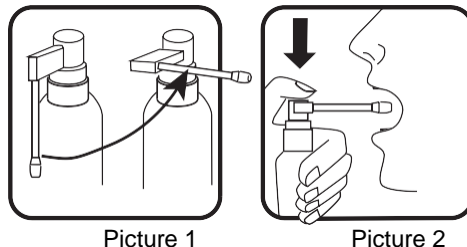
Children under 6 years of age: Spray 1 puff for every 4 kilograms of body weight, up to maximum of 4 puffs, every 1½ to 3 hours.

Do not use the spray continuously for more than 7 days, except if your doctor or dentist tells you to.

How to use Orosoothe Spray

The first time you use the spray you need to press the metering pump down firmly several times to fill the dispenser and produce a proper spray.

1. Turn the spray arm as shown in picture 1.
2. Point the spray arm at the sore part of your mouth as shown in picture 2.
3. Press the plunger down firmly with your thumb or index finger. Apply the correct number of sprays, according to the instructions on dosage.



Picture 1

Picture 2

Talk to your doctor or pharmacist if you feel that the medicine is too strong or too weak.

If you use more Orosoothe 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 Orosoothe Spray

Do not take double dose to make up for a missed dose. Do not worry. Take the next dose as planned.

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.

Some side effects could be serious. If you have any of the side effects listed below, seek medical help 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 which may be potentially life-threatening.

If any of the below side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

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

Very rare: may affect up to 1 in 10,000 people

- 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 (an anaphylactic reaction) which may be potentially life-threatening. In this case you should seek immediate medical assistance or go to hospital straight away.

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 HPRA Pharmacovigilance; Website: www.hpra.ie; By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OROSOOTHE SPRAY

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

Orosoothe Spray may be used for 6 months after first application, providing that the expiry date has not passed. 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.

Do not store above 25°C. Do not refrigerate or freeze. Store in the original package.

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. FURTHER INFORMATION

What Orosoothe Spray contains

The active substance is 0.15% w/v benzydamine hydrochloride.

The other ingredients are glycerol, sodium saccharin, ethanol (96%), sodium hydrogen carbonate, polysorbate 20, methyl parahydroxybenzoate (E218), fresh peppermint mouthwash flavour and purified water.

Please see section 2 for information on some of the ingredients.

What Orosoothe Spray looks like and content of the pack.

Orosoothe Spray is an oromucosal spray (mouth or throat spray). It is a clear solution that comes in a plastic bottle fitted with a metered dose valve pump. Each bottle contains 30ml of solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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For any information about this medicine, please contact the Marketing Authorisation Holder, details provided above.

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