Focus Pharmaceuticals Ltd
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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.

This medicine is not available without prescription. Always use this medicine exactly as described in this leaflet. If you are unsure about any aspect of the treatment prescribed to you, ask your doctor or pharmacist for advice before using this medicine.

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

Other medicines and Benzydamine Spray
Tell your doctor, dentist or pharmacist if you are taking any other medicines, including those to treat colds andflu.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

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

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are generally minor.

If you have any of the following side effects while taking the medicine, stop using it and call your doctor immediately or go to hospital straight away:

- Itchy rash, sometimes with pale, raised areas of skin with red edges (urticaria).
- Your skin becoming more sensitive to sunlight than normal causing an itchy, red, scaly rash, swelling or blistering.
- Tightening of the throat or chest making it difficult to breathe.

Unlikely (up to 1 in 100 people):

- Feeling of numbness in your mouth.
- A tingling feeling in your mouth, tongue or fingers that seems to appear as you continue to use the spray.

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

- Allergic reaction (hypersensitivity), anaphylactic shock, signs of which may include difficulty breathing, chest pain or chest tightness, and/or swelling in the arms or legs, or severe itching (pruritus) or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, and which may be potentially life-threatening.
- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyes, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.

See section 2 (Benzydamine Spray contains methyl parahydroxybenzoate and propylene glycol) for side effects that may be caused by some of the active ingredients in your 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 25°C. 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 if you notice any damage to the spray canister 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 ingredients are: glycerol, carbomer 20, sodium chloride, ethanol 96%, methyl parahydroxybenzoate, anised oil (contains ethanol 95%), peppermint oil (contains propylene glycol), water (see section 2).

What Benzydamine Spray looks like and contains:

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 with a metering pump (a pump that delivers a measured amount of medicine) and nozzle (spray arm).

Each spray container holds 30 ml of medicine.

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For help and advice on how to use this medicine contact your doctor.

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