

## Package leaflet: Information for the user

### **Benzydamine 0.15%w/v Mouthwash** 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 Mouthwash is and what it is used for
2. What you need to know before you use Benzydamine Mouthwash
3. How to use Benzydamine Mouthwash
4. Possible side effects
5. How to store Benzydamine Mouthwash
6. Contents of the pack and other information

#### **1. What Benzydamine Mouthwash is and what it is used for**

**Benzydamine 0.15%w/v Mouthwash (called Benzydamine Mouthwash throughout the rest of the leaflet) is used for treating pain and inflammation (redness, swelling and a feeling of heat) in the throat or mouth.** Benzydamine Mouthwash contains benzydamine hydrochloride, one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

#### **What this medicine does**

Benzydamine Mouthwash 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 Mouthwash 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 Mouthwash**

### **Do not use Benzydamine Mouthwash**

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 Mouthwash

- If you have a history of asthma
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

Be careful not to splash the mouthwash in your eyes. If you get it in your eyes accidentally, wash them **immediately** with cold water.

### **Other medicines and Benzydamine Mouthwash**

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 using this medicine.

### **Driving and using machines**

Benzydamine Mouthwash has negligible influence on the ability to drive and use machines.

### **Benzydamine Mouthwash 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)
- The alcohol (ethanol) content in Benzydamine Mouthwash is 8.1% w/v which is equivalent to 1215 mg per 15 ml of solution
- Propylene glycol – this may cause skin irritation.

## **3. How to use Benzydamine Mouthwash**

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.

**Do not use** the mouthwash continuously **for more than 7 days**, except if your doctor tells you to.

The mouthwash should generally be used undiluted, but if ‘stinging’ occurs you can dilute it with water to reduce this effect.

Benzydamine Mouthwash is for use in the throat or mouth. It should be rinsed around the mouth or used as a gargle according to the following instructions:

The recommended dose is:

**Adults including the elderly**

- The usual dose is 15ml used every 1½ to 3 hours.
- Using the measuring cup provided pour out 15ml of the mouthwash (up to the top mark on the cup saying 15).
- Rinse the 15ml of mouthwash around your mouth or use it as a gargle, for 20 to 30 seconds then spit it out. **Do not swallow the mouthwash.**
- Wash the measuring cup after use and keep it safe ready for your next dose.

**Use in children and adolescents**

- This mouthwash should not be used by children aged 12 years or under.
- Children over 12 should follow the instructions given above for adults.

**If you use more Benzydamine Mouthwash than you should**

If you use too much Benzydamine Mouthwash or if you accidentally swallow it, contact your doctor or pharmacist for advice.

**If you forget to use Benzydamine Mouthwash**

- If you forget to use your mouthwash, do not worry. Use it as soon as you remember and then carry on using it every 1½ to 3 hours as before.
- Do not use double the amount of mouthwash 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.

**If you have any of the following side effects while taking your medicine tell your doctor immediately or go to hospital straight away:**

- Allergic reaction (Hypersensitivity)  
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, and which may be potentially life-threatening
- Tightening of the throat or chest making it difficult to breathe.

Other side effects seen with Benzydamine Mouthwash, which may occur:

**Uncommon: may affect up to 1 in 100 people**

- A feeling of numbness in your mouth.
- A stinging feeling in your mouth – the mouthwash may be diluted with water if you experience stinging. This should help to reduce the stinging effect.

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

- 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, sometimes with blisters.

See section 2 (Benzydamine Mouthwash contains methyl parahydroxybenzoate, ethanol and propylene glycol) for side effects that may be caused by some of the non-active ingredients in your medicine.

### **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](http://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 Mouthwash**

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 bottle label (indicated by “EXP”). The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the bottle in the outer carton.

Once you have opened the mouthwash do not keep it for more than 6 months.

Do not use this medicine if you notice any visible signs of deterioration of your medicine such as discolouration or the solution becoming cloudy. 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 Mouthwash contains**

- The active substance is benzydamine hydrochloride. Each 15ml dose contains 22.5mg benzydamine hydrochloride.
- The other ingredients are glycerol, polysorbate 20, sacharrin sodium, ethanol 96%, methyl parahydroxybenzoate, quinoline yellow (E104), patent blue V (E131), aniseed flavour (contains ethanol 95%), peppermint flavour (contains propylene glycol), water. (See section 2, Benzydamine Mouthwash contains methyl parahydroxybenzoate, ethanol and propylene glycol.)

### **What Benzydamine Mouthwash looks like and contents of the pack**

Benzydamine Mouthwash is a clear green mouthwash with a smell of peppermint. It is contained in a clear glass bottle fitted with a tamper-evident, child-resistant closure. A measuring cup is also provided.

Each bottle of Benzydamine Mouthwash contains 300ml of mouthwash.

**Marketing Authorisation Holder**

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

**Manufacturer**

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