**Package leaflet: Information for the user**
**Benzydamine Hydrochloride 0.15%w/v Mouthwash**

**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 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, pharmacist or nurse. 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**
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## 1. What Benzydamine Mouthwash is and what it is used for
The name of your medicine is Benzydamine 0.15%w/v Mouthwash (called Benzydamine Mouthwash in this leaflet). Benzydamine Mouthwash contains the active substance benzydamine hydrochloride, which belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.
Benzydamine Mouthwash 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
- Pain after dental surgery

## 2. What you need to know before you use Benzydamine Mouthwash
Do not use Benzydamine Mouthwash:
if you are allergic (hypersensitive) to benzydamine hydrochloride or any of the other ingredients of Benzydamine Mouthwash (listed in Section 6).
**Warnings and precautions**
Talk to your doctor, dentist or pharmacist before using Benzydamine Mouthwash:
- if you have a history of asthma
- if you are allergic to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs).

If you are not sure if any of the above applies to you, talk to your doctor, dentist or pharmacist before using Benzydamine Mouthwash.
Be careful not to splash the mouthwash into your eyes. If you get it in your eyes accidentally, wash them **immediately** with cold water.
**Other medicines and Benzydamine Mouthwash**
Please tell your doctor, dentist or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
**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. You should not use Benzydamine Mouthwash during pregnancy unless clearly necessary and advised by your doctor. If you need treatment the lowest dose for the shortest time possible should be used.
Do not take Benzydamine Mouthwash if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Benzydamine Mouthwash during the first 6

months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Benzydamine Mouthwash can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

**Benzydamine Mouthwash contains:**

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'. This product contains glycerol which may cause headache, stomach upset and diarrhoea.

This product contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

This medicinal product contains 10.1 vol % ethanol (alcohol), i.e. up to 1200mg per dose, equivalent to 30ml beer, 12.5ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

## 3. How to use Benzydamine Mouthwash

Always use Benzydamine Mouthwash exactly as your doctor, dentist or pharmacist has told you. You should check with your doctor, dentist or pharmacist if you are not sure.

Do not get Benzydamine Mouthwash in or near your eyes. **If any Benzydamine Mouthwash gets into your eyes, wash them immediately with cold water.**

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

Benzydamine 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:

**Adults, the elderly and children over 12 years:**

the usual dose is 15ml every 1½ to 3 hours as required for pain relief. Rinse or gargle, then spit out. Do not swallow.

Use the measuring cup provided to measure the dose.

**Children under 12 years:** this medicine should not be used by children under 12 years.

Contact your doctor, dentist or pharmacist if your symptoms worsen or they do not improve.

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

If you use too much or you accidentally swallow large quantities of Benzydamine Mouthwash, contact your doctor, dentist or pharmacist for advice.

**If you forget to use Benzydamine Mouthwash**

Do not use a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you have any further questions about the use of this medicine, ask your doctor, dentist 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 following side effects listed below, seek immediate medical help:**

- Serious allergic reaction (anaphylactic shock) signs of which may include difficulty in 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

**Other side effects include the following, if they get serious, 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 in breathing and wheezing
- Itching

- Skin rash
- Your skin becoming more sensitive to sunlight than normal causing an itchy, red, scaly rash, sometimes with blisters

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

- Skin redness or swelling
- Allergic reaction (hypersensitivity)

If this mouthwash stings your mouth, the next dose may be diluted with water to reduce this effect.
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**

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 the Yellow Card Scheme at 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. Store in the original package.
This medicinal product does not require any special temperature storage conditions. Do not use this medicine after the expiry date, which is stated on the bottle and carton.
Discard the opened mouthwash 12 months after first using.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

**What Benzydamine Mouthwash contains**

The active ingredient is Benzydamine hydrochloride. Each 15ml contains 22.5mg benzydamine hydrochloride.
The other ingredients are glycerol, ethanol, methyl parahydroxybenzoate (E218), saccharin sodium (E954), sodium hydrogen carbonate, polysorbate 20, mint flavour, and purified water.

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

Benzydamine Mouthwash is a clear, colourless liquid, available in a 100ml and 300ml bottle with a screw cap and a plastic measuring cup.
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Manufacturer**

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