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, dentist 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, dentist or pharmacist. This includes any possible side effects not listed in this leaflet.
- 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 Oroeze is and what it is used for
2. What you need to know before you use Oroeze
3. How to use Oroeze
4. Possible side effects
5. How to store Oroeze
6. Contents of the pack and other information

1. What Oroeze is and what it is used for

Oroeze is used for treating pain and inflammation (redness, swelling and a feeling of heat) in the throat or mouth. Oroeze contains benzydamine hydrochloride, one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

What this medicine does
Oroeze 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

Oroeze 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 Oroeze

Do not use Oroeze
If you are allergic (hypersensitive) to benzydamine or any of the other ingredients of Oroeze (see section 6 ‘What Oroeze contains’).

Warnings and precautions
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 Oroeze
Tell your doctor, dentist or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility
If you are pregnant, thinking of becoming pregnant or breast-feeding ask your doctor, dentist or pharmacist for advice before using Oroeze.

Important information about some of the non-active ingredients in Oroeze
Some of the non-active ingredients in your medicine may cause side effects:

- Methyl parahydroxybenzoate - this may cause allergic reactions (possibly delayed)
- Propylene glycol – this may cause skin irritation

3. How to use Oroeze

Unless your doctor or dentist has advised otherwise, always use Oroeze as described in this leaflet. Check with your doctor, dentist or pharmacist if you are not sure.

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

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

Oroeze 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 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 is safe ready for your next dose.

Use in Children
- 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 Oroeze than you should
If you use too much Oroeze, or if you accidentally swallow it, contact your doctor, dentist or pharmacist for advice.

If you forget to use Oroeze
- 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 product, ask your doctor, dentist or pharmacist.

4. Possible side effects

Like all medicines, Oroeze 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 your medicine tell your doctor immediately or go to the hospital straight away:
- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. If the swelling affects your throat and makes breathing difficult and swallowing difficult, 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, sometimes with blisters.
- Tightening of the throat or chest making it difficult to breathe.

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.

See section 2 (Important information about some of the non-active ingredients in Oroeze) 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, dentist 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oroeze

Keep out of the sight and reach of children.

Do not use after the expiry date 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 25ºC. 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 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 Oroeze 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 for important information about some of these non-active ingredients.)

What Oroeze looks like and contents of the pack

Oroeze 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 Oroeze contains 300ml of mouthwash.

Marketing Authorisation Holder

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