

## (benzydamine hydrochloride)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start taking 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 have told you.

- This medicine is available without prescription. However, you still need to use it carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your doctor, dentist or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

Your medicine is called Difflam 0.15% w/v Oral Rinse but will be referred to as Difflam Oral Rinse throughout the leaflet.

**What is in this leaflet:**

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

**1 What Difflam Oral Rinse is and what it is used for**

Difflam Oral Rinse contains the active substance benzydamine hydrochloride and belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

Difflam Oral Rinse 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
- Discomfort associated with dentures or dental work.

**2 What you need to know before you use Difflam Oral Rinse****Do not use Difflam Oral Rinse if**

- you are allergic to benzydamine hydrochloride
- you are allergic to any of the other ingredients of Difflam Oral Rinse (see section 6).

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Difflam Oral Rinse:

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

If any of these apply to you, talk to your doctor, dentist or pharmacist.

**Other medicines and Difflam Oral Rinse**

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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 taking this medicine.

You should not use Difflam Oral Rinse 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.

**Difflam oral rinse contains:**

This medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

Methyl-para-hydroxy benzoate may cause allergic reactions (possibly delayed)

This medicine contains 1126 mg of alcohol (ethanol) in each 15 ml dose. The amount in 15 ml of this medicine is equivalent to less than 30 ml beer or 12 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 0.025 mg benzyl alcohol in each 175 microlitre dose which is equivalent to 0.14 mg/ml. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicinal product contains mint flavour with benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool. These substances may cause allergic reactions.

**3 How to use Difflam Oral Rinse****Important:**

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

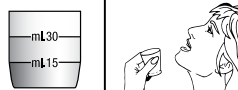
**If you get Difflam Oral Rinse in your eyes**

Do not use Difflam Oral Rinse in or near your eyes.

**If any Oral Rinse gets in your eyes, wash them immediately with cold water.**

**How much Difflam Oral Rinse to use**

- **Adults, adolescents and elderly:** The usual dose is 15 ml of solution to be used every 1½ to 3 hours. Use the measuring cup provided to measure the dose.
- **Children:** This medicine is not suitable for children aged 12 years or under.

**How to use the Oral Rinse**

The solution should be rinsed around the mouth or used as a gargle for 20 to 30 seconds and then spat out.

This solution should not be swallowed.

This solution should not be used for more than 7 days unless your doctor or dentist tells you to.

**If your symptoms worsen or do not improve contact your doctor or dentist.**

**If you use more Difflam Oral Rinse than you should**

If you take too much or you accidentally swallow large quantities of your medicine, contact immediately your doctor or pharmacist for advice.

#### **If you forget to use Difflam Oral Rinse**

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

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

#### **4 Possible side effects**

Like all medicines Difflam Oral Rinse 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 immediate medical help:**

- 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.

**Other side effects include the following, if they get serious, please 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 breathing and wheezing
- Itching
- Skin rash.

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

- Skin redness or swelling
- Allergic reaction (Hypersensitivity).

If this solution stings your mouth, the next dose can be diluted with some 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**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

#### **5 How to store Difflam Oral Rinse**

- **Keep out of the sight and reach of children.**
- Do not store above 30°C.
- Do not refrigerate or freeze.
- Do not leave uncartoned bottle in direct sunlight.
- Do not use Difflam Oral Rinse after the expiry date on the bottle or carton. The expiry date refers to the last day of that month.
- 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.
- If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will know what to do.

#### **6 Contents of the pack and other information**

##### **What Difflam Oral Rinse contains**

- The active substance is benzydamine hydrochloride
- Each 15ml contains 22.5mg benzydamine hydrochloride
- The other ingredients are: ethanol (96%), glycerol, saccharin sodium, mouthwash flavour 52 503/T firmenich, polysorbate 20, methyl hydroxybenzoate (E218), and quinoline yellow (E104), patent blue V (E131), and purified water.

For advice on what to do if you are allergic to any of these ingredients see section 2.

##### **What Difflam Oral Rinse looks like and contents of the pack**

- Clear, green solution.
- Each bottle contains 300ml and a 30ml graduated measuring cup.

##### **Manufacturer and Licence Holder**

Manufactured by 3M Health Care Limited, Morley Street, Loughborough, Leicestershire, LE11 1EP, UK and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

Difflam Oral Rinse is a registered trademark of Cooper Consumer Health SAS.

**P** PL 15184/1811 Difflam 0.15% w/v Oral Rinse

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