PATIENT INFORMATION LEAFLET

Difflam™ Oral Rinse
(benzydamine hydrochloride)

Read all of this leaflet carefully because it contains important information for 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.

In this leaflet:
1. What Difflam Oral Rinse is for
2. 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. Further information

1. WHAT DIFFLAM ORAL RINSE IS FOR
Difflam Oral Rinse 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. 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).

If either of these applies to you, talk to your doctor, dentist or pharmacist.

Taking other medicines
Tell your doctor, dentist or pharmacist before using Difflam Oral Rinse if you are taking any other medicines, even medicines obtained without a prescription.

Pregnancy and breastfeeding
If you are pregnant, trying to become pregnant or breast-feeding ask your doctor, dentist or pharmacist for advice before using Difflam Oral Rinse.

Important information about some of the ingredients of Difflam Oral Rinse
This product contains only a small amount of ethanol (alcohol). Each 15ml of solution contains 1.5ml of ethanol.

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

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 15ml 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 your symptoms worsen or they do not improve.

If you use more Difflam Oral Rinse than you should
It should not cause you any problems if you accidentally take too much or you swallow some of your medicine. If you have any concerns, contact your doctor or pharmacist.

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.

• Itching
• Skin rash
• Skin redness or swelling
• Difficulty breathing and wheezing
• Numbness or stinging in the mouth or throat.

If this solution stings your mouth, the next dose can be diluted with some water to reduce this effect.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**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.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. **HOW TO STORE DIFFLAM ORAL RINSE**

*Keep out of the sight and reach of children.*

Do not use Difflam Oral Rinse after the expiry date (Exp) stated on the carton and the bottle. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not refrigerate or freeze. Store in an upright position.

If you doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

If your medicine appears to be discoloured or shows any other signs of deterioration, please return to your pharmacist who will advise you.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. **FURTHER INFORMATION**

**What Difflam Oral Rinse contains**

The active substance is benzydamine hydrochloride. Each 15ml contains 22.5mg benzydamine hydrochloride.

The other ingredients are ethanol, glycerol, saccharin sodium, mouthwash flavour 52 503/T, polysorbate 20, methyl parahydroxybenzoate (E218), 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**

Difflam Oral Rinse is a clear, green coloured gargle solution. It comes in a 300ml bottle with a metal screw cap and a 20ml graduated, plastic measuring cup.

**Manufacturer**


Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents Drive, Prudhoe, Northumberland, NE42 6PX.

PL No: 21828/0585

Leaflet issue and revision date: 12.05.14

Difflam™ is a trademark of Meda AB.

To request a copy of this leaflet in large print or audio, please call 01302 365000 and ask for the Regulatory Department.
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Do not store above 30°C. Do not refrigerate or freeze. Store in an upright position.
Store in the original package. If you store the product without the original carton, make sure it is kept out of direct sunlight.

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Only keep it if your doctor tells you to.

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