Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Difflam oral rinse 0.15% w/v gargle, which will be called Difflam rinse throughout this leaflet.

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

1. What Difflam rinse is and what it is used for
Difflam rinse contains the active ingredient benzydamine, which belongs to a group of medicines called local analgesics and anti-inflammatories. Difflam rinse is used to relieve painful inflammatory conditions of the mouth and throat including:
- Pharyngitis (sore throat) cause by removal of the tonsils or use of naso-gastric tube (feeding tube).
- Pharyngitis, and mouth ulcers caused by radiation therapy
- After dental operations.

2. What you need to know before you use Difflam Rinse
Do not use Difflam rinse:
- If you are allergic to benzydamine or any of the other ingredients of this medicine ( listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

Warnings and precautions
Talk to your doctor or pharmacist before using Difflam rinse. Try not to get Difflam rinse in your eyes. If you do, rinse thoroughly with clean water.

Take special care with Difflam:
- If you have a history of Asthma.
- If you are allergic to acetylsalicylic acid or to other anti-inflammatory painkillers called NSAIDs.

Children
Difflam rinse is not suitable for children aged 12 years or under.

Other medicines and Difflam rinse
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are you planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
There are no known effects on driving or operating machinery.

Difflam rinse contains ethanol, glycerol and methylhydroxybenzoate
Difflam rinse contains 96% ethanol (alcohol), i.e. up to 14.4 ml per dose, equivalent to 288ml beer, 120ml 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.
Difflam rinse also contains Glycerol, which if swallowed may cause headache, stomach upset and diarrhoea. Do not swallow the rinse. Always spit out the rinse after gargling.

3. How to use Difflam Rinse
Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and the elderly
Rinse or gargle with 15ml (about 1 tablespoonful) every 1.5 to 3 hours as required to relieve pain.
After gargling, spit out the rinse and do not swallow it.

Use in Children
Difflam rinse is not suitable for children aged 12 years or under. Difflam rinse should usually be used undiluted, but if ‘stinging’ occurs the rinse may be diluted with water. You should not use Difflam rinse for more than 7 days at a time unless your doctor tells you to.

If you use more Difflam rinse than you should
If you accidentally swallow a dose (15ml), it is unlikely to cause harm. In the case of someone deliberately swallowing a large quantity, go to the accident and emergency department of your hospital immediately. Signs of overdose are the same as for alcohol intoxication, i.e. drunkenness.

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. All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:
Mouth numbness or ‘stinging’ sensations, itching, rash, nettle rash, skin sensitivity to the sun, spasm of the vocal cords causing difficulty in breathing, and asthma-like symptoms. Severe allergic reactions (anaphylactic reaction) which can be potentially life-threatening.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

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

5. **How to store Difflam Rinse**
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 original container after “EXP”. The expiry date refers to the last day of that month. Store in the original carton below 30°C. Do not refrigerate or freeze. 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 Difflam rinse contains:**
Each 15ml contains 22.5mg benzydamine hydrochloride equivalent to 0.15% w/v. The other ingredients are: ethanol (96 per cent), glycerol, saccharin sodium, mouthwash flavour, 52 503/T firmenich, polysorbate 20, methyl-hydroxybenzoate (E218), and quinolone yellow (E104), patent blue V (E131), and purified water.

**What Difflam rinse looks like and contents of the pack**
Difflam 15mg rinse, gargle, is a green solution with pleasant taste. It is contained in a clear, glass bottle with an aluminium screw cap containing 300ml and a 20ml graduated, plastic measuring cup.

**Marketing Authorisation Holder and Manufacturer**
**Marketing Authorisation Holder**
Meda Health Sales Ireland Limited
Unit 34/35, Block A
Dunboyne Business Park,
Dunboyne,
Co. Meath

**Manufacturer**
3M Health Care Limited
Morley Street,
Loughborough,
Leicestershire,
LE11 1EP, UK

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