

Package leaflet: Information for the user
Difflam Oral Rinse 0.15% w/v, Gargle
benzydamine hydrochloride

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

Always take this medicine exactly as described in this leaflet or as your doctor 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 or pharmacist. 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.

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) caused 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.

Difflam Oral Rinse is for oromucosal use only and should not be swallowed.

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, breast-feeding and fertility

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. You should not use Difflam 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.

Driving and using machines

There are no known effects on driving or operating machinery.

Difflam rinse contains ethanol, methyl parahydroxybenzoate (E218) and mint flavour

This product 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.

Do not swallow the rinse and always spit out the rinse after gargling.

This product also contains:

- methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
- mint flavour with benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool. Benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool may cause allergic reactions
- less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

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 15 ml (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 (15 ml), it is unlikely to cause harm. If you take too much or you accidentally swallow large quantities of your medicine, contact immediately your doctor or pharmacist for advice.

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.

Very common ($\geq 1/10$)

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very rare ($< 1/10,000$)

Not known (cannot be estimated from the available data)

The most common side effects are numbness and a stinging feeling in the mouth.

Respiratory, thoracic and mediastinal disorders

Very rare: Laryngospasm or bronchospasm.

Gastrointestinal disorders

Uncommon: Oral numbness (hypoesthesia) and a stinging feeling in the mouth (oral pain).

Skin and subcutaneous tissue disorders

Very rare: Hypersensitivity reactions which may be associated with pruritus, urticaria, photosensitivity reaction and rash

Frequency not known: Angioedema

Immune system disorders

Frequency not known: Anaphylactic reaction (hypersensitivity)

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.

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 reporting systems listed below:

Ireland

HPRA Pharmacovigilance,

Website: www.hpra.ie.

Malta

ADR Reporting

Website:

www.medicinesauthority.gov.mt/adrportal

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. 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 15 ml contains 22.5 mg benzydamine hydrochloride equivalent to 0.15% w/v.

The other ingredients are: ethanol (96%), glycerol, saccharin and sodium hydrogen carbonate, mint flavour, polysorbate 20, methyl parahydroxybenzoate (E218), quinoline yellow (E104), patent blue V (E131), and purified water.

What Difflam rinse looks like and contents of the pack

Difflam rinse, gargle, is a green solution with pleasant taste. It is contained in a clear, glass bottle with a screw cap containing 300 ml and a 30 ml graduated, plastic measuring cup.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Cooper Consumer Health B.V.
Verrijn Stuartweg 60, Diemen,
Noord-Holland, 1112 AX,
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Manufacturer

Aziende Chimiche Riunite Angelini Francesco
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