

It comes in a 200 ml bottle with a measuring cup.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK.

Package leaflet: Information for the patient

Difflam 0.15 % Sore Throat Rinse

Benzylamine hydrochloride

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 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.

What is in this leaflet:

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

1. What Difflam Sore Throat Rinse is and what it is used for

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

Difflam Sore Throat Rinse works by stopping pain and swelling (inflammation). It is used to treat many painful conditions of the throat including:

- Sore throat.

2. What you need to know before you use Difflam Sore Throat Rinse

Do not use Difflam Sore Throat Rinse if

- you are allergic to benzylamine hydrochloride
- you are allergic to any of the other ingredients of Difflam Sore Throat Rinse (see section 6).

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

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Difflam Sore Throat 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, talk to your doctor, dentist or pharmacist.

Other medicines and Difflam Sore Throat 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.

Do not take Difflam Sore Throat Rinse if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and

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heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Difflam Sore Throat Rinse during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Difflam Sore Throat Rinse can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Difflam sore throat 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 Sore Throat Rinse

Important:

Always use Difflam Sore Throat 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 Sore Throat Rinse in your eyes

Do not use Difflam Sore Throat Rinse in or near your eyes. **If any Sore Throat Rinse gets in your eyes, wash them immediately with cold water.**

How much Difflam Sore Throat 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 Sore Throat Rinse



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

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

If you use more Difflam Sore Throat 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 Sore Throat 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 Sore Throat 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Difflam Sore Throat Rinse

Keep out of the sight and reach of children.

Do not use Difflam Sore Throat Rinse after the expiry date on the bottle. The expiry date refers to the last day of that month.

If you store the product without the original carton, make sure it is kept out of the direct sunlight.

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

6. Contents of the pack and other information

What Difflam Sore Throat Rinse contains

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

The other ingredients are ethanol, glycerol, saccharin, sodium hydrogen carbonate, mouthwash flavour 52 503/T, polysorbate 20, methyl parahydroxybenzoate, quinoline yellow (E104) and patent blue V (E131), purified water. For advice on what to do if you are allergic to any of these ingredients see section 2.

What Difflam Sore Throat Rinse looks like

Difflam Sore Throat Rinse is a clear, green coloured gargle solution.