

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

Marketing Authorisation Holder
Cooper Consumer Health B.V.
Verrijn Stuartweg 60,
1112AX Diemen – Netherlands

Manufacturer
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**If this leaflet is difficult to see
or read or you would like it in
a different format, please contact**
Cooper Consumer Health B.V.
Verrijn Stuartweg 60,
1112AX Diemen – Netherlands

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 benzydamine
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 (inflamma-
tion). 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 benzydamine
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.

You should not use Difflam Sore Throat
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 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.



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.