**Package leaflet: Information for the user**
**Difflam**
**Spray 0.15% w/v,**
**Oromucosal Spray**
benzydamine 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 or pharmacist has told 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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

**What is in this leaflet:**

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


## 1. What Difflam spray is and what it is used for

Difflam spray contains the active ingredient benzydamine, which belongs to a group of medicines called local analgesics and anti-inflammatories. Difflam spray is used along with other treatments to relieve painful inflammatory conditions of the mouth and throat.

## 2. What you need to know before you use Difflam Spray

**Do not use Difflam spray:**
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 or precautions**
Talk to your doctor or pharmacist before using Difflam spray. Try not to get Difflam spray in your eyes. If you do, wash them thoroughly with clean water. Stop using if the condition does not improve or gets worse.

**Other medicines and Difflam Spray**
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 using this medicine. You should not use Difflam Spray 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 operation machinery.

**Difflam spray contains alcohol, methyl parahydroxybenzoate (E218) mint flavour and sodium**

This medicine contains:

- 14 mg of alcohol (ethanol) in each puff. The amount in 1 puff of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- less than 1 mmol sodium (23 mg) per dose of 8 puffs, that is to say essentially 'sodium-free'.
- 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. These substances may cause allergic reactions.

## 3. How to use Difflam spray

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adult and the elderly**
4 to 8 puffs, every 1 ½ to 3 hours.

**Children (6-12 years)**
4 puffs, every 1 ½ to 3 hours.

**Children under 6 years**
1 puff per 4kg body weight up to a maximum of 4 puffs every 1 ½ to 3 hours.
Spray on to the sore area. You should not use Difflam spray for more than 7 days at a time unless your doctor tells you to.

**Follow instructions and pictures below.**

1. The spray bottle should be held in an upright position.
2. Lift the nozzle through 90 degrees. Do not raise the nozzle more than shown.
3. When using for the first time, press the green plunger down several times until a fine spray appears out of the end of the nozzle. It is now ready for use.
4. Aim the nozzle at the affected area of the mouth and press down on the green plunger again. Each time you press down one puff is released.
5. After applying the correct number of puffs wipe the end of the nozzle with a tissue.
6. Push the nozzle down as shown. This prevents any more puffs being released.
7. Do not attempt to insert anything into the end of the nozzle. If a blockage occurs please return the spray to your pharmacist.

**If you take more Difflam spray than you should**
If you accidentally swallow a dose, it is unlikely to cause any harm. If you take too much or you accidentally swallow large quantities of your medicine, contact immediately your doctor or pharmacist for advice.

**If you have any further questions on the use of this product, 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 'stinging' sensations (stop use if stinging persists), 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 (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1,000 to <1/100)
Rare (≥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 and a stinging feeling in the mouth.
The stinging has been reported to disappear upon continuation of the treatment, however if it persists it is recommended that treatment be discontinued.

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 reactions (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.

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 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 Spray

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.
. Do not store above 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 any medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Difflam spray contains:**
Each puff (175 microliters) contains 262. 5 micrograms of the active ingredient benzydamine hydrochloride (0.15% w/v). The other ingredients are ethanol (96%), glycerol, saccharin, mint flavour, polysorbate 20, methyl parahydroxybenzoate (E218), sodium hydrogen carbonate, and purified water.

**What Difflam spray looks like and contents of the pack**
Difflam spray is a metered dose pump spray solution. Difflam spray is presented in a box containing a 30ml plastic bottle with a 170 microliter metering valve spray pump.

**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**

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