

Package leaflet: Information for the patient

Difflam 0.15% Spray

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 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 substance benzydamine hydrochloride and belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDs.

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

- Mouth ulcers
- Teething
- Sore throat
- Sore tongue or gums
- Discomfort associated with dentures or dental work.

2. What you need to know before you take Difflam Spray

Do not use Difflam Spray if:

- You are allergic to benzydamine hydrochloride
- You are allergic to any of the other ingredients in Difflam Spray (listed in section 6).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Difflam Spray:

- 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 or pharmacist.

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 taking this medicine.

Do not take Difflam Spray 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 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 Spray 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 Spray 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 Spray Contains:

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.

Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose of 8 puffs, that is to say essentially 'sodium-free'.

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 Spray

Important:

Always use Difflam Spray exactly as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Do not use Difflam Spray in or near your eyes. If any spray gets in your eyes, wash them immediately with cold water.

How much Difflam Spray to use

- **Adults, adolescents and elderly** – spray 4 - 8 puffs to the sore area every 1½ to 3 hours.
- **Children 6-12 years of age** – spray 4 puffs to the sore area every 1½ to 3 hours.
- **Children under 6 years of age** – spray 1 puff for every 4 kilograms of body weight, up to a maximum of 4 puffs, to the sore area every 1½ to 3 hours.

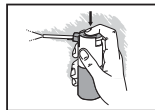
Contact your doctor if your symptoms worsen or they do not improve.

How to use the spray

1. To use the spray, hold the bottle in an upright position.
2. Lift the spray-tube through 90° until it is horizontal. Do not raise the spray-tube more than shown in the diagram.



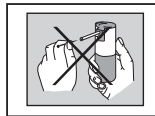
3. The first time you use the spray you need to prime it. Point the spray-tube away from your face. Press down firmly on the green plunger until a fine spray appears from the end of the spray-tube. The spray is now ready to use.



4. Aim the spray-tube at the sore part of your mouth or throat and press down on the green plunger again. One press releases one puff.
5. After spraying the desired number of puffs, wipe the end of the spray-tube with a tissue. This helps to stop it becoming blocked.
6. Push the spray-tube back down as shown in the diagram. This stops any puffs being accidentally released.



7. Do not push anything into the end of spray-tube if it becomes blocked. Return the spray to your pharmacist.



If you use more Difflam Spray 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 Spray

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 Spray 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)

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 Diffiam Spray

Keep out of the sight and reach of children.

Do not use Diffiam Spray after the expiry date on the bottle. The expiry date refers to the last day of that month.

Store in an upright position. Do not store above 30 °C. Do not store in the refrigerator or freezer.

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 Diffiam Spray contains

The active substance is benzydamine hydrochloride at a concentration of 0.15%. Each puff contains 262.5 micrograms of benzydamine hydrochloride.

The other ingredients are glycerol, saccharin, sodium bicarbonate, ethanol, methylhydroxy-benzoate, mouthwash flavour, polysorbate 20 and purified water.

For advice on what to do if you are allergic to any of these ingredients see section 2.

What Diffiam Spray looks like and content of the pack

Diffiam Spray is an oromucosal or mouth spray. It is a clear, colourless liquid that comes in a plastic bottle fitted with a metered dose valve pump. This means it provides a measured amount of spray each time it is used. Each bottle contains 30 ml of liquid and comes in a carton.

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, United Kingdom.