

Package leaflet: information for the user

## Difflam 3 mg Lozenges, lemon flavour

Benzylamine Hydrochloride

# Difflam<sup>TM</sup>

**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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- 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.

What is in this leaflet:

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

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

Difflam contains the active substance benzylamine hydrochloride, which is a local anti-inflammatory agent. Difflam is used in adults and children above 6 years of age for symptomatic local treatment for the relief of pain and irritation of the mouth and throat.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

### 2. What you need to know before you take Difflam Lozenges

**Do not take Difflam Lozenges:**

- If you are allergic to benzylamine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from a condition known as phenylketonuria.
- If you are allergic to salicylic acid or to other anti-inflammatory painkillers called NSAIDs (e.g. ibuprofen).

**Warning and precautions**

**Talk to your doctor or pharmacist before taking this medicine:**

- If you have a history of Asthma.

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- If after using the lozenges the pain in your mouth or throat gets worse or does not improve within 3 days or you appear feverish or have other symptoms, you should speak to your doctor or pharmacist.

**Taking other medicines and Difflam Lozenges**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Difflam Lozenges are not expected to affect other medicines, however if you are not sure, please ask your doctor or pharmacist about other medicines obtained without a prescription.

**Difflam Lozenges with food, drink**

Food and drink have no influence.

**Pregnancy, breast-feeding**

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.

Difflam lozenges should not be used during pregnancy. Difflam lozenges should not be used during breast-feeding.

**Driving and using machines**

Difflam Lozenges does not affect your ability to drive or use machines.

**Difflam Lozenges contains**

**Isomalt** (which is a type of sugar): If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Aspartame:** This medicine contains 3.26 mg aspartame in each lozenge which is equivalent to 3.26 mg/3237 mg. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

### 3. How to take Difflam Lozenges

Always take 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.

The recommended dose is:

Adults and children over 6 years old: one lozenge 3 times a day. Do not take more than 3 lozenges per day.

**Use in children**

Children from 6 to 11 years old: this medicinal product should be administered under an adult supervision.

**Please turn over**

Children under the age of 6 years old should not be given Difflam Lozenges.

Let one lozenge dissolve slowly in your mouth up to three times a day.

Do not swallow. Do not chew.

Difflam should not be used for more than 7 days.

If after using the lozenges your throat gets worse or does not feel better, speak to your pharmacist or doctor.

#### **If you take more Difflam Lozenges than you should**

If you accidentally take too many lozenges, you should contact your pharmacist, doctor or nearest hospital casualty department immediately. Always take the labelled medicine package with you, whether there are any lozenges left or not.

### **4. Possible side effects**

Like all medicines, this medicine can cause side-effects, although not everybody gets them.

**Allergic reactions are rare, but can be serious.**

**Tell your doctor immediately if you get any sudden swelling in the mouth/ throat, difficulty breathing, rash or itching especially if affecting the whole body.**

#### **Uncommon (may affect up to 1 in 100 people):**

- Skin sensitivity to sunlight (causing a rash or sunburn).

#### **Rare (may affect up to 1 in 1,000 people):**

- Burning sensation or dryness of the mouth. If this happens to you, try sipping a glass of water to reduce the effect.

#### **Very rare (may affect up to 1 in every 10,000 people)**

- Sudden swelling in the mouth/throat and mucous membranes (angioedema).
- Difficulty breathing (laryngospasm).

#### **Not known (frequency cannot be estimated from the available data):**

- Local loss of sensitivity of the oral mucosa (hypoesthesia oral)
- Allergic 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 the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme ([www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Difflam Lozenges**

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 label after EXP.

The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Difflam Lozenges contains:**

- The active substance is benzydamine
- Each lozenge contains 3 mg of benzydamine hydrochloride (equivalent to 2.68 mg benzydamine).
- The other ingredients are isomalt (E 953), aspartame (E951), citric acid monohydrate, lemon flavour, mint flavour, quinoline yellow (E104), indigotin dye (E132).

#### **What Difflam Lozenges looks like and contents of the pack**

Difflam Lozenges are yellow-green, square shaped lozenges with a central cavity, wrapped in food paper. Difflam Lozenges are provided in packs of 20 lozenges and 30 lozenges. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisation Holder is Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

The Manufacturers are A.C.R.A.F. S.p.A., Via Vecchia del Pinocchio, 22 60131 – Ancona, Italy

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