

Package leaflet: information for the user

Difflam 3 mg Lozenges, mint flavour

Benzylamine Hydrochloride

DifflamTM

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Difflam Lozenges carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact your doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Difflam contains benzylamine, which helps to relieve pain and irritation of the mouth and throat.

2. Before you take Difflam Lozenges

Do not take Difflam Lozenges:

- If you have had an allergic (hypersensitivity) reaction to benzylamine or to any of the other ingredients. You suffer from a condition known as phenylketonuria.
- You are allergic to salicylic acid or to other anti-inflammatory painkillers called NSAIDs (e.g. ibuprofen).

Warning and precautions

Talk to your doctor 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 7 days, or you appear feverish or have other symptoms, you should speak to your doctor or pharmacist.

Other medicines and Difflam Lozenges

Tell your doctor or pharmacist if you are taking or have recently taken 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 and drink

Food and drink have no influence.

Pregnancy and breast-feeding

You should tell your doctor or pharmacist if you are pregnant, planning to become pregnant or are breastfeeding.

He/She will then decide whether you should take Difflam Lozenges.

Driving and using machines

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

Important information about some of the ingredients of Difflam Lozenges

Difflam Lozenges contain 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 medicine.

Difflam Lozenges contains aspartame a source of phenylalanine. Maybe harmful for people with phenylketonuria.

Please turn over

3. How to take Difflam Lozenges

Always take Difflam Lozenges exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

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

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

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 Lozenges 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, Difflam Lozenges may 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.

Occasionally, some people feel a burning sensation and dryness of the mouth. If this happens to you, try sipping a glass of water to reduce the effect. Rarely, people taking medicines with benzydamine may experience sensitivity to light.

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). 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 Difflam Lozenges 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 30°C.

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

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Difflam Lozenges contains:

Each lozenge contains 3 mg benzydamine hydrochloride (equivalent to 2.68 mg benzydamine). The other ingredients are isomalt (E 953), aspartame (E951), levomenthol, 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 green, square shaped lozenges with a central cavity, wrapped in food paper. Difflam Lozenges are provided in packs containing 20 lozenges and 30 lozenges.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop's Stortford, CM22 6PU

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