

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Difflam 3 mg Lozenges, lemon flavour.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each lozenge contains 3 mg of benzydamine hydrochloride equivalent to 2.68 mg benzydamine.

Excipients with known effects: each lozenge contains 3183 mg of Isomalt (E 953) 3.26 mg of Aspartame (E 951) , Mint Fragrance with Benzyl Alcohol, Citronellol, d- Limonene, Eugenol, Geraniol, Linalool and Lemon Fragrance with Benzyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol, Linalool, Butylated hydroxyanisole.

For the full list of excipients, see section 6.1

## **3 PHARMACEUTICAL FORM**

Lozenge.

Green square-shaped lozenges, with a central cavity.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Symptomatic treatment for the relief of pain and irritation of mouth and throat.

### **4.2 Posology and method of administration**

#### *Posology*

Adults and children over 6 years of age: one lozenge 3 times a day.

The treatment must not exceed 7 days.

#### *Paediatric population*

Children 6-11 years of age:

The medicinal product should be administered under adult supervision.

Children below 6 years of age:

Due to the type of the pharmaceutical form, the administration should be restricted to children of more than 6 years of age.

#### *Method of administration*

For oropharyngeal use.

Lozenge should be dissolved slowly in the mouth.

Do not swallow. Do not chew.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

Benzydamine use is not advisable in patient with hypersensitivity to salicylic acid or other NSAIDs.

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Caution should be exercised in these patients.

In a minority of patients, buccal/pharyngeal ulceration may be caused by serious disease processes. Patients whose symptoms worsen or do not improve within 3 days, or who appear feverish or have other symptoms, must therefore seek the advice of their doctor or dentist as appropriate.

Difflam contains:

- **Aspartame:** aspartame is hydrolysed in the gastrointestinal tract when orally ingested. One of the major hydrolysis products is phenylalanine that may be harmful for people with phenylketonuria.
- **Isomalt:** patients with rare hereditary problems of fructose intolerance should not take this medicine.
- **Mint Fragrance with Benzyl Alcohol, Citronellol, d- Limonene, Eugenol, Geraniol, Linalool and Lemon Fragrance with Benzyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol, Linalool.** These may cause allergic reactions.
- **Butylated hydroxyanisole which is a component of lemon fragrance:** It may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed in humans.

#### 4.6 Fertility, Pregnancy and lactation

##### *Pregnancy*

There are no or limited amount of data from the use of benzydamine in pregnant women, and animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Difflam lozenges is not recommended during pregnancy.

##### *Breastfeeding*

There is insufficient information on the excretion of benzydamine in human milk.

Difflam lozenges should not be used during breastfeeding.

#### 4.7 Effects on ability to drive and use machines

Difflam has no or negligible influence on the ability to drive and use machine, when it is used at the recommended dose.

#### 4.8 Undesirable effects

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness

The following rate values have been used: Very common ( $\geq 1/10$ ), Common ( $\geq 1/100$  to  $<1/10$ ), Uncommon ( $\geq 1/1,000$  to  $<1/100$ ), Rare ( $\geq 1/10,000$  to  $<1/1,000$ ) and Very rare ( $<1/10,000$ ), not known (cannot be estimated from the available data).

System-Organ Class	Frequency	Undesirable effect
Immune system disorders	<i>Not Known</i>	Anaphylactic reaction, Hypersensitivity reaction
Respiratory, thoracic, and mediastinal disorders	<i>Very rare</i>	Laryngospasm
Gastrointestinal Disorders	<i>Rare</i> <i>Not known</i>	Burning mouth, Dry mouth Hypoaesthesia oral

<b>Skin and subcutaneous tissue disorders</b>	<i>Uncommon</i>	Photosensitivity
	<i>Very rare</i>	Angioedema

### **Reporting of suspected adverse reactions**

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](http://www.mhra.gov.uk/yellowcard) or search for MHRA yellow car in the Google Play or Apple App Store.

## **4.9 Overdose**

### *Symptoms*

No overdose with the lozenge formulation has been reported. However, very rarely in children excitation, convulsions, sweating, ataxia, tremor and vomiting have been reported after the oral administration of benzydamine dosages about 100 times higher than those of the lozenge.

### *Management*

In the event of acute overdose only symptomatic treatment is possible; the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient carefully observed and given supportive treatment. Adequate hydration must be maintained.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: other throat preparations, *ATC code*: R02AX03.

#### *Clinical efficacy and safety*

Clinical studies demonstrate that benzydamine is effective in relieving suffering from localised irritation processes of the mouth and pharynx. In addition, benzydamine possesses a moderate local anaesthetic effect.

In a randomized, active-controlled clinical trial, an initial reduction of pain was observed in 87% of patients with acute sore throat at 1 minute after administration of one 3 mg benzydamine lozenge, reaching 91% of patients after 2 minutes. After 15 minutes from the administration, a meaningful relief of pain was observed in approximately 83% of patients. The improvement in difficulty in swallowing and swollen sensation were also observed. The very good safety profile of benzydamine was confirmed.

## 5.2 Pharmacokinetic properties

### *Absorption*

The absorption through the mucosa of the mouth and pharynx was demonstrated by the presence of measurable quantities of benzydamine in the human plasma.

### *Distribution*

About 2 hours after the 3 mg lozenge administration, benzydamine peak plasma values of 37.8 ng/ml with an AUC of 367 ng/ml\*h were observed. However, these levels are not sufficient to produce pharmacological systemic effects.

When locally applied benzydamine has been shown to accumulate in inflamed tissues where it reaches effective concentrations because of its capacity to penetrate the epithelial lining

### *Biotransformation and elimination*

The excretion occurs mainly in the urine and mostly in the form of inactive metabolites or conjugation products.

## 5.3 Preclinical safety data

Developmental and peri-post natal toxicity was seen in reproductive toxicity studies in rats and rabbits at plasma concentration much higher (up to 40 times) than those observed after a single therapeutic oral dose. No teratogenic effects were seen in those studies. Available kinetic data do not allow to establish the clinical relevance of the reproductive toxicity studies. As the preclinical studies had shortcomings and therefore are of restricted value, they do not provide additional information relevant for the prescriber beyond that included in other sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Isomalt (E953)

Aspartame (E951)

Citric acid, monohydrate

Lemon flavour

Mint flavour

Quinoline yellow (E104)

Indigotine dye (E132).

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

4 years

## **6.4 Special precautions for storage**

Store in original package in order to protect from moisture.

## **6.5 Nature and contents of container**

Lozenge is wrapped in paraffin paper.

Ten lozenges form one stick, packaged in printed polyethylene-paper-aluminium trilaminated material.

Lozenges can be packaged also in PVC/PE/PVDC – ALU blister.

Pack sizes of 20 or 30 lozenges.

Not all pack size may be marketed.

## **6.6 Special precautions for disposal**

No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Mylan Products Ltd.,  
Station Close, Potters Bar,  
Hertfordshire, EN6 1TL, UK

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 46302/0096

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

26/06/2005

**10     DATE OF REVISION OF THE TEXT**

08/11/2023