SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Difflam 3 mg Lozenges, mint 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) and 3.5 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

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

The treatment must not exceed 7 days.

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.

Oropharingeal use.

Lozenge should be dissolved slowly in the mouth.

Do not swallow. Do not chew.

4.3 Contraindications

Known hypersensitivity to the active substance or to any of the excipients.

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. Once of the minor hydrolysis products is phenylalanine That may be harmful for people with phenylketonuria.

- Isomalt: and 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

There are not adequate data from the use of benzydamine in pregnant and breast-feeding women. Excretion into breast milk has not been studied. Animal studies are insufficient with respect to effects on pregnancy and lactation (see section 5.3). The potential risk for humans is unknown.

Difflam should not be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

The local use of benzydamine at the recommended dose does not affect the ability to drive and use machines.

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 (≥ 1/10), Common (≥ 1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥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	Not Known	Anaphylactic reaction, Hypersensitivity reactions
Respiratory, thoracic, and mediastinal disorders	Very rare	Laryngospasm
Gastrointestinal Disorders	Rare Not known	Burning mouth, Dry mouth Hypoaesthesia oral
Skin and subcutaneous tissue disorders	Uncommon Very rare	Photosensitivity 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 or search for MHRA yellow car in the Google Play or Apple App Store.

4.9 Overdose

Symptoms
No overdosage 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 overdosage 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

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

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

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.

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),

Menthol,

Citric acid,

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

Cooper Consumer Health B.V.,
Verrijn Stuartweg 60, 1112 AX Diemen,
The Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

PL 60682/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/06/2005

10 DATE OF REVISION OF THE TEXT

02/07/2025