Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Difflam Oral Rinse 0.15% w/v, gargle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15ml contains 22.5mgbenzydamine hydrochloride equivalent to 0.15% w/v

Excipients: Each 15ml dose contains 15mg of methyl parahydroxybenzoate (E218), 1126 mg of ethanol, mint flavour (contains allergens including 2 mg benzyl alcohol) and <1mmol of sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gargle.

Clear, green solution with pleasant taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Difflam Oral Rinse is a locally acting analgesic and anti-inflammatory treatment for the relief of painful inflammatory conditions of the mouth and throat including:

TRAUMATIC CONDITIONS: Pharyngitis following tonsillectomy or the use of a naso-gastric tube;

INFLAMMATORY CONDITIONS: Pharyngitis, aphthous ulcers and oral ulceration due to radiation therapy;

DENTISTRY: For use after dental operations.
Benzydamine exerts an anti-inflammatory and analgesic action by stabilising the cellular membrane and inhibiting prostaglandin synthesis.

4.2 Posology and method of administration

Rinse or gargle with 15 ml (approximately 1 tablespoonful) every 1.5 to 3 hours as required for pain relief.

Not suitable for children aged 12 years or under.

The solution should be expelled from the mouth after use.

Difflam Oral Rinse should generally be used undiluted, but if 'stinging' occurs the rinse may be diluted with water.

Uninterrupted treatment should not exceed seven days, except under medical supervision.

ELDERLY: No special dosage recommendations are made for elderly patients.

4.3 Contraindications

Use in patients with a known hypersensitivity to the active ingredient, benzydamine hydrochloride, or to any of the other ingredients.

4.4 Special warnings and precautions for use

Avoid contact with eyes.

Difflam Oral rinse is for oromucosal use only and should not be swallowed.

This product contains 1126 mg of alcohol (ethanol) in each 15 ml dose. The amount in 15 ml of this medicine is equivalent to less than 30 ml beer or 12 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This product also contains:

- methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed)
- mint flavour with benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool. Benzyl alcohol, cinnamyl alcohol, citral, citronellol, eugenol, geraniol, isoeugenol, limonene and linalool may cause allergic reactions
- less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

Benzydamine use is not advisable in patients with hypersensitivity to acetylsalicylic 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.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Difflam should not be used in pregnancy or lactation unless considered essential by the physician. There is no evidence of a teratogenic effect in animal studies.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

The most common side effects are numbness and a stinging feeling in the mouth.

Respiratory, thoracic and mediastinal disorders
Very rare: Laryngospasm or bronchospasm.

Gastrointestinal disorders
Uncommon: Oral numbness (hypoesthesia) and a stinging feeling in the mouth (oral pain).

Skin and subcutaneous tissue disorders
Very rare: Hypersensitivity reactions which may be associated with pruritus, urticaria, photosensitivity reaction and rash
Frequency not known: Angioedema

Immune system disorders
Frequency not known: Anaphylactic reactions (which can be potentially life-threatening), hypersensitivity reactions

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

4.9 Overdose

Intoxication is only expected in case of accidental ingestion of large quantities of benzydamine (> 300 mg)

Symptoms associated with ingested overdose of benzydamine are mainly gastrointestinal symptoms and symptoms of the central nervous system. Most frequent gastrointestinal symptoms are nausea, vomiting, abdominal pain, and esophageal irritation. Symptoms of the central nervous system include dizziness, hallucinations, agitation, anxiety, and irritability. In acute overdose only symptomatic treatment is possible. Patients should be kept under close observation and supportive treatment should be given. Adequate hydration must be maintained.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antiinflammatory and antirheumatic agents, nonsteroids / Anti-inflammatory preparations, non-steroids for topical use,
ATC code: M01AX07

Mechanism of action
The indazole analogue benzydamine has physicochemical properties and pharmacological activities which differ from those of the aspirin-like NSAIDs. Unlike aspirin-like NSAIDswhich are acids or metabolised to acids, benzydamine is a weak base. In further contrast, benzydamine is a weak inhibitor of the prostaglandin synthesis. Only at concentration of 1 mM and above benzydamine effectively inhibits cyclooxygenase and lipooxygenase enzyme activity. It mostly exerts its effects through inhibition of the synthesis of pro-inflammatory cytokines including tumor necrosis factor-alpha (TNF-α) and Interleukin-1β (IL-1β) without significantly affecting other pro-inflammatory (IL-6 and 8) or anti-inflammatory cytokines (IL-10, IL-1 receptor antagonist). Further mechanisms of action are hypothesised including the inhibition of the oxidative burst of neutrophils as well as membrane stabilisation as demonstrated by the inhibition of granule release from neutrophils and the stabilisation of lysosomes. The local anaesthetic activity of the compound has been related to an interaction with cationic channels.

Pharmacodynamic effects
Benzydamine specifically acts on the local mechanisms of inflammation such as pain, oedema or granuloma. Benzydamine topically applied demonstrates anti-inflammatory activity reducing oedema as well as exudate and granuloma formation. Further, it exhibits analgesic properties if pain is caused by an inflammatory condition and local anaesthetic activity. Hyperthermia, which is indicative of systemic functional involvement, is poorly affected by benzydamine.

Clinical efficacy and safety
Benzydamine was evaluated topically as spray or rinse for the relief of painful inflammatory conditions of the mouth and throat through its local analgesic, anaesthetic, and anti-inflammatory action.
In clinical studies Difflam spray or rinse have shown benefit in traumatic conditions such as pharyngitis following tonsillectomy or the use of an endotracheal tube. Difflam further showed efficacy in the relief of inflammatory conditions including pharyngitis relieving pain and dysphagia. In clinical studies benzydamine reduced pain, inflammation and ulceration of the oral mucosa associated with radiation therapy. Rinsing with benzydamine after dental surgery reduced pain and inflammation and improved healing of the surgical site. Patients with aphthous ulcer reported pain relief after rinsing with benzydamine solution.

5.2 Pharmacokinetic properties

Oral doses of benzydamine are well absorbed and plasma drug concentrations reach a peak fairly rapidly and then decline with a half-life of about 13 hours. Less than 20% of the drug is bound to plasma proteins.

Although local drug concentrations are relatively large, the systemic absorption of mouthwash-gargle doses of benzydamine is relatively low compared to oral doses. This low absorption should greatly diminish the potential for any systemic drug side-effects when benzydamine is administered by this route.

Benzydamine is metabolized primarily by oxidation, conjugation and dealkylation.

5.3 Preclinical safety data

Non-Clinical Data reveal no special hazards for humans based on conventional studies of safety pharmacology, repeated toxicity, genotoxicity, cardiogenic potential, and toxicity to reproduction.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (96%) Glycerol
Saccharin
Sodium hydrogen carbonate
Mint Flavour
Polysorbate 20
Methyl parahydroxybenzoate (E218)
Quinoline Yellow (El04)
Patent blue V (E131)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Four years.

6.4 Special precautions for storage

Do not refrigerate or freeze. Keep the bottle in the outer carton.

6.5 Nature and contents of container

A clear, glass bottle with a screw cap containing 300 ml with graduated, 30ml measuring cup.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Cooper Consumer Health B.V.
Verrijn Stuartweg 60
Diemen
Noord-Holland
1112 AX
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA25506/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 06 September 2007

10 DATE OF REVISION OF THE TEXT

January 2026