SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benzydamine Hydrochloride 0.15%w/v Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzydamine hydrochloride 0.15%w/v

Each spray contains 255 micrograms of benzydamine hydrochloride. One ml of spray contains 1.5mg benzydamine hydrochloride. Each spray contains 0.17ml solution.

Excipients with known effect

Ethanol (96%) 13.6mg per spray

Methyl parahydroxybenzoate (E 218) 0.17mg per spray

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal Spray Solution

A clear, colourless liquid with a characteristic mint odour and a pH of between 5 - 7 in a multidose spray container fitter with a metering pump

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Benzydamine Spray is a locally acting analgesic and anti-inflammatory treatment for the throat and mouth.

It is especially useful for the relief of pain in traumatic conditions such as following tonsillectomy or the use of a naso-gastric tube, dental surgery.

4.2 Posology and method of administration

Posology

Adults, adolescents and elderly: 4 to 8 sprays, 1½-3 hourly

Children (6-12 years): 4 sprays, 1½-3 hourly

Children under 6 years: One spray to be administered per 4kg bodyweight, up to a maximum of 4 sprays, 1½-3 hourly

Elderly: Because of the small amount of drug applied, elderly patients can receive the same dose as adults

Method of administration

For oral administration. The spray must be primed before use. No less than 3 actuations are required for priming. The full dose is obtained on the fourth actuation.

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 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.

Avoid contact with the eyes.

If the condition is aggravated or not improved use should cease.

Contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed)

This medicine contains less than 1 mmol sodium (23 mg) per dose of 8 puffs, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no clinical data from the use of Benzydamine Spray during pregnancy.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed.

It is not known if the systemic Benzydamine Spray exposure reached after topical

administration can be harmful to an embryo/fetus.

Therefore, Benzydamine Spray should not be used during pregnancy unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible..

Breastfeeding

It is unknown whether benzydamine hydrochloride / metabolites are excreted in human milk. Benzydamine Spray should not be used during breastfeeding unless considered essential by the physician.

Fertility

There is no evidence of a teratogenic effect in studies (see section 5.3). It is not known whether treatment with Benzydamine Spray affected fertility in humans.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

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

The following frequency categories are 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).

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). The stinging has been reported to disappear upon continuation of the of the treatment, however if it persists it is recommended that treatment be discontinued.

Skin and subcutaneous tissue disorders

Very rare: pruritus, urticaria, photosensitivity reaction and a rash

Frequency not known: Angioedema

Immune system disorders

Frequency not known: Anaphylactic reaction which can be potentially life-

threatening. Hypersensitivity reactions

Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

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 Card in the Google Play or Apple App Store.

4.9 Overdose

Benzydamine is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. Intoxication is only to be expected if large quantities of Benzydamine Spray are swallowed (>300mg).

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 agents for local oral treatment, ATC code: A01AD02.

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 NSAIDs which 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 1mM 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 tumour 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 stabilization 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

In a clinical study in 24 patients with pharyngitis following tonsillectomy rinsing with Difflam 0.15% 5 times a day for 6 days significantly better and more rapidly relieved throat pain, difficulty in swallowing and improved clinical signs including hyperaemia and oedema versus placebo on day 7. Similar results were found in other studies in patients with tonsillitis or pharyngitis or following dental surgery. The gargling with 30ml 0.075% benzydamine prior to the induction of anaesthesia in 58 adults undergoing general anaesthesia with endotracheal tube intubation significantly reduced postoperative sore throat versus water control for the first 24 hours whereas aspirin gargles reduced it for 4 hours.

In a clinical study with 48 patients rinsing four times daily with 0.15% benzydamine during a 3 to 5 week radiotherapy of oral cancer provided significant pain relief and reduction of size and severity of mucositis in the oropharynx. Similar effects were seen in a study in patients undergoing chemotherapy for oral cancer. In a study in 67 patients with severe oropharyngeal mucositis following radiotherapy who rinsed with benzydamine solution pain with swallowing, hyperaemia and severity of mucositis were significantly reduced compared to placebo treatment within the first three treatment days.

A higher incidence of transient numbness and stinging was noted among the patients using benzydamine that was attributed to the medication’s local anaesthetic effect.

The topical application of Difflam cream 3% 3 times daily for 6 days in 50 patients with soft tissue injuries significantly better relieved pain, tenderness, erythema, functional impairment and swelling compared to placebo on day 6.

Overall, benzydamine was well tolerated in clinical trials.

5.2 Pharmacokinetic properties

Following oral administration, benzydamine is rapidly absorbed from the gastrointestinal tract and maximum plasma levels reached after 2-4 hours. The most important aspect of the tissue distribution of benzydamine is its tendency to concentrate at the site of inflammation.

About half of the benzydamine is excreted unchanged via the kidney at a rate of 10% of the dose within the first 24 hours. The remainder is metabolised, mostly to N-Oxide.

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

Glycerol

Ethanol 96%

Methyl parahydroxybenzoate (E218)

Saccharin sodium (E954)

Sodium hydrogen carbonate

Polysorbate 20

Mint flavour SC-5230-AT (maltodextrin and menthol)

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years unopened

Use within 12 months of opening

6.4 Special precautions for storage

There are no special requirements for storage

6.5 Nature and contents of container

15ml or 30ml class III amber glass bottle with a plastic metering pump and protective cap consisting of PP/POM/Rubber/Stainless steel/LDPE/PE/PEK

15ml or 30ml polyethylene bottle fitted with a dosing pump and a spray actuator

15ml bottle will allow for approximately 85 actuations

30ml bottle will allow for approximately 170 actuations

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Manx Healthcare Ltd
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Bosworth Avenue
Tournament Fields
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8 MARKETING AUTHORISATION NUMBER(S)

PL 14251/0056

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/03/2025

10 DATE OF REVISION OF THE TEXT

28/08/2025