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

A clear, colourless liquid with a characteristic mint odour and a pH of between 5 - 7 in a multidose spray container fitted 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 used to treat various painful oropharyngeal conditions such as mouth ulcers, sore throat, sore mouth or gums, dental pain.

4.2 Posology and method of administration

Posology

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

Paediatric population

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

Children under 6 years: One spray to be administered per 4 kg 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

Oromucosal 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 benzydamine hydrochloride 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 13.6 mg of alcohol (ethanol) in each spray. The amount in 1 spray of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per dose, 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 foetus. 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/foetus.

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.

There is no evidence of a teratogenic effect in animal studies.

From the 20th week of pregnancy onward, Benzydamine Spray use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, Benzydamine Spray should not be given unless clearly necessary. If Benzydamine Spray is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to Benzydamine Spray for several days from gestational week 20 onward. Benzydamine Spray should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:

- cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension);

- renal dysfunction (see above);

the mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses;

- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, Benzydamine Spray is contraindicated during the third trimester of pregnancy (see sections 4.3)

Breastfeeding

Benzydamine Hydrochloride Spray should not be used during breastfeeding unless considered essential by the physician.

Fertility

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

Adverse events are listed by System Organ Class:

Frequencies are defined using the following convention:

Very common (≥1/10), Common (≥1/100, <1/10), Uncommon (≥1/1000, <1/100), Rare (≥1/10000, <1/1000), Very rare (<1/10000), Not known (cannot be estimated from the available data).

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

System organ class	**Frequency**	**Undesirable effects**
Immune system disorders	Not known	Anaphylactic reactions, Hypersensitivity reactions
Respiratory, thoracic and mediastinal disorders	Very rare	Laryngospasm or bronchospasm
Gastrointestinal disorders	Uncommon	Oral numbness and a stinging feeling in the mouth. 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 rash
	Not known	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 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 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 oesophageal 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 anti-inflammatory and antirheumatic agents, non-steroids /Anti-inflammatory preparations, non-steroids for topical use

ATC code: M01AX07/M02AA05

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 proinflammatory cytokines including tumour necrosis factor-alpha (TNF-α) and Interleukin-1β (IL-1β) without significantly affecting other proinflammatory (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 Benzydamine 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 30 ml 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 Benzydamine 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

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

30ml class III amber glass bottle fitted with a plastic metering pump, protective cap and dispenser.

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

30ml bottle will allow for approximately 175-176 actuations

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Farmak Pharmaceuticals UK Ltd
First Floor, 47 Queen Street,
Hull, HU1 1UU,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 59209/0091

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/01/2026

10 DATE OF REVISION OF THE TEXT

20/01/2026