SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oroeze 0.15% w/v Mouthwash

Benzydamine 0.15% w/v Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzydamine hydrochloride 0.15% w/v.

Each 15ml dose contains 22.5mg benzydamine hydrochloride.

Excipients with known effect
Ethanol (96%) 8.1%w/v
Methyl parahydroxybenzoate 0.1 %w/v
It also contains propylene glycol.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Mouthwash.

A clear green solution with an odour of peppermint

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oroeze/Benzydamine 0.15% w/v Mouthwash is indicated in adults and children aged 13 years and over.

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.

4.2 Posology and method of administration

Posology

Adults and elderly: Rinse or gargle with 15 ml (approximately 1 tablespoonful) every 1½ to 3 hours as required for pain relief.

The solution should be expelled from the mouth after use.

Oroeze/Benzydamine 0.15% w/v Mouthwash 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.

Paediatric population

Oroeze/Benzydamine 0.15% w/v Mouthwash should not be used in children aged 12 years or under.

Method of administration

Oromucosal administration.

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

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

Oroeze/Benzydamine 0.15% w/v Mouthwash should generally be used undiluted, but if 'stinging' occurs the rinse may be diluted with water.

Avoid contact with eyes.

Oroeze/Benzydamine 0.15% w/v Mouthwash contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed). It also contains propylene glycol which may cause skin irritation.

The alcohol (ethanol) content in Benzydamine Mouthwash is 8.1% w/v. which is equivalent to 1215 mg per 15 ml of solution.

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 Oroeze/Benzydamine 0.15% w/v Mouthwash 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 Oroeze/Benzydamine 0.15% w/v Mouthwash exposure reached after topical administration can be harmful to an embryo/fetus.

Therefore, Oroeze/Benzydamine 0.15% w/v Mouthwash 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.

Breast-feeding

Oroeze/Benzydamine 0.15% w/v Mouthwash should not be used during lactation 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

Oroeze/Benzydamine 0.15% w/v Mouthwash has no or negligible influence on the ability to drive and use machines.

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 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 reaction which can be potentially life-threatening and hypersensitivity reactions[i]
Respiratory, thoracic and mediastinal disorders	Very rare	Laryngospasm or bronchospasm
Gastrointestinal disorders	Uncommon	Oral numbness (hypothesia) 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
	Not known	Angiodema

i) Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisations 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 Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms
Oroeze/Benzydamine 0.15% w/v Mouthwash is unlikely to cause adverse systemic effects, even if accidental ingestion should occur. Intoxication is only expected in case of accidental ingestion of large quantities of benzydamine (> 300 mg).Intoxication is only to be expected if large quantities of Oroeze/Benzydamine 0.15% w/v Mouthwash are swallowed.

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.

Management

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.

Benzydamine exerts an anti-inflammatory and analgesic action by stabilising the cellular membrane and inhibiting prostaglandin synthesis.

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 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.

5.2 Pharmacokinetic properties

Absorption:

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.

Biotransformation:

Benzydamine is metabolised primarily by oxidation, conjugation and dealkylation.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol

Ethanol (96%)

Methyl parahydroxybenzoate

Saccharin sodium

Polysorbate 20

Quinoline yellow (E104)

Patent blue V (E131)

Peppermint flavour (contains propylene glycol)

Aniseed flavour (contains ethanol 95%)

Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

Use within 6 months of opening.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear type III glass bottle with child-resistant, tamper-evident cap containing 300ml of Mouthwash. Supplied with a measuring cup.

6.6 Special precautions for disposal

No special requirements for disposal.

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

7. MARKETING AUTHORISATION HOLDER

Focus Pharmaceuticals Ltd
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20046/ 0048

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/12/2024

10 DATE OF REVISION OF THE TEXT

08/10/2025