Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Orosoothe 0.15% w/v Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of the solution contains 1.5mg of benzydamine hydrochloride. Each puff (0.17 ml) contains 255 micrograms of benzydamine hydrochloride (0.15% w/v).

Excipient(s) with known effect:
Contain methyl parahydroxybenzoate and ethanol. For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray. A metered dose pump spray solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an adjunct in the symptomatic relief of painful inflammatory conditions of the throat and mouth.

4.2 Posology and method of administration

For oromucosal administration.

ADULTS AND ELDERLY: 4 to 8 puffs, 1½-3 hourly.

CHILDREN (6-12): 4 puffs, 1½-3 hourly.

CHILDREN UNDER 6: One puff to be administered per 4 kg body weight, up to a maximum of 4 puffs, 1½-3 hourly.

Because of the small amount of drug applied, elderly patients can receive the same dose as adults.
The spray should be directed onto the affected area. Uninterrupted treatment should not exceed 7 days, except under medical supervision.

4.3 Contraindications

Hypersensitivity to benzydamine hydrochloride or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Avoid contact with the eyes.

Hypersensitivity reaction can occur with local use of medicinal products, especially in prolonged exposure. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted.

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.

Excipient Warnings:
Methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

This medicine contains 8.5mg of alcohol (ethanol) in each puff. The amount in 1 puff of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Orosoothe Spray 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

Adverse events are ranked under the heading of the frequency:

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.

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 treatment, however if it persists it is recommended that treatment be discontinued.

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 reaction which can be potentially life- threatening, hypersensitivity.

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 national reporting system:
HPRA PharmacovigilanceWebsite: www.hpra.ie

4.9 Overdose

Orosoothe Spray is unlikely to cause adverse systemic effects when used locally, and risk of overdose is negligible.
Intoxication is only expected in case of accidental ingestion of large quantities of Benzydamine, > 300 mg (one full bottle of Benzydamine Oromucosal Spray contains 45 mg of benzydamine hydrochloride).
Symptoms associated with overdose of ingested 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

Non-steroidal anti-inflammatory drug.

ATC code: A01AD02 (Other agents for local oral treatment). Benzydamine exerts an anti-inflammatory and analgesic action by stabilising the cellular membrane and inhibiting prostaglandin synthesis.

Benzydamine is an indolic nonsteroidal anti-inflammatory drug (NSAID) for systemic and local use. Orosoothe Spray contains benzydamine and is intended for local use. Benzydamine is lipophilic at pH 7.2, has an affinity for membranes and shows membrane stabilising properties with local anaesthetic effects.

Contrary to other NSAIDs, benzydamine does not inhibit the cyclo- nor the lipoxygenase (10(-4) mol/l). In studies on rats, benzydamine was shown to have no ulcerogenic effect on the GI tract. Nacrophage PGE2 synthesis is enhanced at 10(-4) mol/l. Phospholipase A2 as well as the lysophosphatide-acyltransferase is slightly inhibited at benzydamine concentrations greater than 10(-4) mol/l. Benzydamine inhibits the production of proinflammatory cytokines, and can be therefore considered to have an anti-inflammatory action.

5.2 Pharmacokinetic properties

Following local use, benzydamine is very well absorbed through the skin and mucosa and moves into the underlying inflamed tissues to reach concentrations higher than following oral administration. Following local administration, benzydamine is absorbed to the bloodstream to a very limited extent (up to 5 per cent of the dose) and has a negligible systemic effect. Benzydamine is mainly secreted with urine as inactive metabolites or conjugated compounds.

5.3 Preclinical safety data

Preclinical safety data reveal low toxicity of benzydamine. Limited data indicate that benzydamine has no genotoxic and carcinogenic properties. It has no teratogenic effect. Reduced reproduction can be observed in pregnant female rats which are administered doses much higher than those used in human.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sodium saccharin Ethanol (96 per cent)
Sodium hydrogen carbonate Polysorbate 20
Methyl parahydroxybenzoate (E218) Fresh peppermint mouthwash flavour Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

Shelf-life after first opening the container: 6 months.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Store in the original package.

6.5 Nature and contents of container

Orosoothe Spray is presented in a box containing a 30 ml HDPE bottle with a spray pump.

6.6 Special precautions for disposal

None required.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath.
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1113/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd March 2019
Date of last renewal: 14th May 2022

10 DATE OF REVISION OF THE TEXT

December 2023