SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ultra Chloraseptic Sore Throat Pain Relief 0.71% w/v Oromucosal Spray

Oraco Sore Throat Pain Relief Spray 0.71% w/v Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 0.71 % w/v

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Oromucosal Spray

Direct application to the throat by spraying

Clear, colourless to straw coloured liquid

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Symptomatic relief of sore throat pain.

4.2 Posology and method of administration

Posology

Adults and children 13 years and over: Administer 3 sprays (3mg) to the back of the throat. Repeat every 2-3 hours up to a maximum of 8 doses per day.

Paediatric population

Children 6-12 years: Use only under adult supervision. Administer 1 spray (1mg) to the back of the throat. Repeat every 2-3 hours up to a maximum of 8 doses per day. This product is contraindicated in children under 6 years.

Method of administration:

Oromucosal.

Hold breath and spray to the back of the throat.

Do not use in a child who is unable to hold their breath whilst spraying.

Before first use, or after prolonged storage, activate the pump by spraying 3 times away from the face into the sink.

4.3 Contraindications

Children under 6 years.

Epiglottitis.

Known hypersensitivity to benzocaine or any of the excipients listed in section 6.1.

Methaemoglobinaemia.

4.4 Special warnings and precautions for use

Do not administer to children under 6 years.

Do not use for more than 3 consecutive days.

Do not spray into eyes.

If sore throat is severe or persistent, or accompanied by fever, headache or nausea consult your doctor.

You should experience temporary numbness in your throat after using the spray. This indicates that the product is working. Avoid eating or drinking as long as the numbness lasts.

Labelling will include the following information:

> Do not use if you have any difficulty in breathing, noisy breathing or severe difficulty in swallowing.
>
> Do not use if you have been told that you have a rare blood condition called methaemoglobinaemia.

Contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy and lactation. The potential risk for humans is unknown. Therefore, this medicine is not recommended during pregnancy or breast-feeding.

4.7 Effects on ability to drive and use machines

This medicine has no expected effect on the ability to drive and use machines.

4.8 Undesirable effects

Allergic reactions have been reported very occasionally with benzocaine. There have been occasional reports of temporary breathing difficulty, face or mouth swelling.

Methaemoglobinaemia has been reported with benzocaine use.

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: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Pronounced reversible anaesthesia would be observed. No systemic adverse effects are expected due to the poor systemic absorption and low administered dose of benzocaine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R02AD01

Benzocaine is a local anaesthetic of the ester type. The mode of action is a reversible inhibition of the flux of sodium and potassium ions through the axonal membranes of peripheral pain receptors. As a consequence, the depolarisation and propagation of nerve impulses are inhibited.

The onset of action of benzocaine on mucous membranes is rapid due to the spray delivery of the anaesthetic direct to the site of action, rapid absorption, and the surface analgesic effect. The local anaesthesia induced by benzocaine is temporary but this medicine has not been tested for duration of action.

5.2 Pharmacokinetic properties

Benzocaine is absorbed into the mucosal membranes. After systemic absorption, which is negligible, the drug is thought to be metabolised to ethanol and aminobenzoic acid by plasma esterases. Aminobenzoic acid is excreted unchanged or conjugated with glycine to aminohippuric acid in the liver, the metabolites and unchanged benzocaine are excreted in the urine.

5.3 Preclinical safety data

No animal data are available on this medicine. Non-clinical studies on benzocaine showed local irritation and sensation, and methaemoglobinaemia at high doses in some species.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Ethanol
Macrogol 300
Propylene glycol
Glycerol
Cetylpyridinium chloride
Levomenthol
Saccharin Sodium
Sodium dihydrogen phosphate dihydrate
Sodium hydroxide
Purified water.

6.2 Incompatibilities

None known.

6.3. Shelf-Life

36 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Uncoloured, clear or textured Type III glass bottle, containing 15ml of product with a polypropylene/low density polyethylene pump and polypropylene cap.
Or
Amber, clear Type III glass bottle, containing 15ml of product with a polypropylene/polyethylene pump.

6.6. Instruction for Use, Handling and Disposal

None.

7 MARKETING AUTHORISATION HOLDER

Prestige Brands (UK) Ltd
5-7 London Road
St. Albans
AL1 1LA,
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 18259/0001

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

07 July 2000

10 DATE OF REVISION OF THE TEXT

17/06/2025