

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

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

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Benzocaine 0.71 % w/v

Excipients with known

effects: Propylene Glycol and

Ethanol.

For full list of excipients, see section 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, Ultra Chloraseptic Spray is not recommended during pregnancy or breast-feeding.

#### **4.7 Effects on ability to drive and use machines**

Ultra Chloraseptic Spray 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](http://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 Ultra Chloraseptic Spray 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 Ultra Chloraseptic Spray. 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  
Winter spice flavour  
Mint (cool) flavour  
Garden Mint flavour  
Sodium dihydrogen phosphate dihydrate  
Sodium hydroxide  
Purified water

## **6.2 Incompatibilities**

None known.

No data held.

## **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 Special precautions for disposal**

None.

**7 MARKETING AUTHORISATION HOLDER**

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

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 18259/0014

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

04/04/2025

**10 DATE OF REVISION OF THE TEXT**

23/01/2026