

**ULTRA CHLORASEPTIC PAIN RELIEF THROAT SPRAY 0.71% W/V  
OROMUCOSAL SPRAY**

**(Benzocaine)**

**PL 18259/0005**

**UK PAR**

**TABLE OF CONTENTS**

Lay Summary	Page 2
Scientific discussion	Page 3
Steps taken for assessment	Page 11
Summary of Product Characteristics	Page 12
Product Information Leaflet	Page 15
Labelling	Page 17

# **ULTRA CHLORASEPTIC PAIN RELIEF THROAT SPRAY 0.71% W/V OROMUCOSAL SPRAY**

**PL 18259/0005**

## **LAY SUMMARY**

The MHRA granted Prestige Brands (UK) Limited a Marketing Authorisation (licence) for the medicinal product Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray on 07 July 2011. This medicine is available on the General Sales List (GSL) and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray is used to relieve sore throat pain.

This medicine contains the active ingredient benzocaine which belongs to a group of medicines called local anaesthetics. It has a fast action and works by numbing the pain of a sore throat.

This application is a duplicate of a previously granted application for Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001), which was granted to the Marketing Authorisation Holder Prestige Brands (UK) Limited on 07 July 2000 following a change of ownership from PL 00129/0115, Vicks Ultra Chloraseptic held by Procter & Gamble (Health & Beauty Care) Limited.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray outweigh the risks; hence a Marketing Authorisation has been granted.

**ULTRA CHLORASEPTIC PAIN RELIEF THROAT SPRAY 0.71% W/V  
OROMUCOSAL SPRAY**

**PL 18259/0005**

**SCIENTIFIC DISCUSSION**

**TABLE OF CONTENTS**

Introduction	Page 4
Pharmaceutical assessment	Page 5
Non-clinical assessment	Page 8
Clinical assessment (including statistical assessment)	Page 9
Overall conclusions and risk benefit assessment	Page 10

## **INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the MHRA granted a Marketing Authorisation for the medicinal product Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray (PL 18259/0005) to Prestige Brands (UK) Limited on 07 July 2011. This medicine is available on the General Sales List (GSL) and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist and is used for the symptomatic relief of sore throat pain.

This product contains the active ingredient benzocaine, which 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 application was submitted as simple abridged application according to Article 10c (formerly Article 10.1(a)(i)) of Directive 2001/83/EC, cross-referring to Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001) approved on 07 July 2000 to the Marketing Authorisation Holder Prestige Brands (UK) Limited following a change of ownership from PL 00129/0115, Vicks Ultra Chloraseptic held by Procter & Gamble (Health & Beauty Care) Limited.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product.

## **PHARMACEUTICAL ASSESSMENT**

**LICENCE NO:** PL 18259/0005  
**PROPRIETARY NAME:** Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray  
**COMPANY NAME:** Prestige Brands (UK) Limited  
**E.C. ARTICLE:** Article 10(c) of Directive 2001/83/EC  
**LEGAL STATUS:** GSL

### **1 INTRODUCTION**

This is a simple, informed consent application for Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray submitted under Article 10(c) of Directive 2001/83/EC. The application cross-refers to Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001) approved on 07 July 2000, to Prestige Brands (UK) Limited following a change of ownership from PL 00129/0115, Vicks Ultra Chloraseptic held by Procter & Gamble (Health & Beauty Care) Limited.

The current application is considered valid.

### **2 MARKETING AUTHORISATION APPLICATION (MAA)**

#### **2.1 Name(s)**

The proposed name of the product is Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray. The product has been named in line with current requirements.

#### **2.2 Strength, pharmaceutical form, route of administration, container and pack sizes**

The product contains benzocaine 0.71 % w/v and is available in pack sizes of 15ml. It is to be stored in:

- 1) Uncoloured, clear or textured Type III glass bottles, containing 15ml of product with a polypropylene/low density polyethylene pump and polypropylene cap.
- 2) Amber, clear Type III glass bottles, containing 15ml of product with a polypropylene/polyethylene pump.

The proposed shelf life is 36 months with no special storage conditions

The proposed shelf-life and storage conditions are consistent with the details registered for the cross-referenced product.

#### **2.3 Legal status**

On approval, the product will be available on the General Sales List (GSL).

#### **2.4 Marketing Authorisation Holder/Contact Persons/Company**

The proposed Marketing Authorisation Holder is Prestige Brands (UK) Limited, Beechwood 3 Scotlands Drive, Farnham Common, Slough, Berkshire SL2 3ES, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and their CV is included.

#### **2.5 Manufacturers**

The proposed manufacturing site is consistent with that registered for the reference product and evidence of compliance with current Good Manufacturing Practice has been provided.

## **2.6 Qualitative and quantitative composition**

The proposed composition is consistent with the details registered for the reference product.

## **2.7 Manufacturing process**

The proposed manufacturing process is consistent with the details registered for the reference product and the maximum batch size is stated.

## **2.8 Finished product/shelf-life specification**

The proposed finished product specifications are in line with the details registered for the reference product.

## **2.9 Drug substance specification**

The proposed drug substance specifications are consistent with the details registered for the cross-reference product.

## **2.10 TSE Compliance**

No materials of human or animal origin have been used in the manufacture of these products. This is consistent with the reference product.

## **2.11 Bioequivalence**

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001).

## **3 EXPERT REPORT**

The applicant has included detailed pharmaceutical expert report, written by an appropriately qualified person.

## **4. PRODUCT NAME & APPEARANCE**

See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the reference product.

## **5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

The proposed SmPC is consistent with the details registered for the reference product.

## **6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING**

### **PIL**

The patient information leaflet has been prepared in line with the details registered for the reference product.

The applicant has previously submitted results of PIL user testing for the reference product Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001). The results indicate that the PIL is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains. As the leaflet for Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001) and this product is considered the same, no further user testing of the leaflet for this product is necessary. The Marketing Authorisation Holder has provided a report to bridge the leaflet for Ultra Chloraseptic Pain Relief Throat Spray 0.71% w/v Oromucosal Spray (daughter) to the parent leaflet for the reference product (Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001)). This is acceptable.

#### Carton and blister

The proposed artwork complies with the relevant statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

### **7. CONCLUSIONS**

The data submitted with this application is acceptable. The grant of a Marketing Authorisation is recommended.

## **NON-CLINICAL ASSESSMENT**

As this application is identical to the reference product Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001), no new non-clinical data have been supplied with this application and none are required. A non-clinical expert report has been written by a suitably qualified person and is satisfactory.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As the application is for an identical version of an already authorised reference product, it is not expected that the environmental exposure to benzocaine will increase following the marketing approval of the proposed product.

## **CLINICAL ASSESSMENT**

As this application is identical to the reference product Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001), no new clinical data have been supplied with this application and none are required. A clinical expert report has been written by a suitably qualified person and is satisfactory.

The Marketing Authorisation Holder has provided adequate justification for not submitting a Risk Management Plan (RMP). As the application is for an identical version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active ingredient is well-established.

The Marketing Authorisation Holder has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the Marketing Authorisation Holder has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

## **OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT**

### **QUALITY**

The data for this application is consistent with that previously assessed for the reference product and as such have been judged to be satisfactory.

### **NON-CLINICAL**

No new non-clinical data were submitted and none are required for an application of this type.

### **EFFICACY**

This application is identical to the previously granted application for Ultra Chloraseptic Anaesthetic Throat Spray (PL 18259/0001), granted to Prestige Brands (UK) Limited on 07 July 2000.

### **SAFETY**

No new or unexpected safety concerns arise from this application.

### **PRODUCT LITERATURE**

The SmPC, PIL and labelling are satisfactory and consistent with that for the reference product.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. The name of the product in Braille appears on the outer packaging.

### **BENEFIT/RISK ASSESSMENT**

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the reference product. Extensive clinical experience with benzocaine is considered to have demonstrated the therapeutic values of the compound. The benefit/risk is therefore considered to be positive.

**ULTRA CHLORASEPTIC PAIN RELIEF THROAT SPRAY 0.71% W/V  
OROMUCOSAL SPRAY**

**PL 18259/0005**

**STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the Marketing Authorisation Application on 10 March 2011
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 21 March 2011
3	Following assessment of the application the MHRA requested further information on 04 April 2011.
4	The applicant responded to the MHRA's request, providing further information on 17 May 2011.
5	The application was determined on 07 July 2011.

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Ultra Chloraseptic Pain Relief Throat 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.

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 other ingredients.

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**

None known

#### **4.6 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**

None expected

#### **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.

#### **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.

##### Treatment of overdose

N/A

### **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 glycerine 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  
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  
Beechwood, 3 Scotlands Drive, Farnham Common  
Slough, Berkshire SL2 3ES  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 18259/0005

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

07/07/2011

**10 DATE OF REVISION OF THE TEXT**

07/07/2011

# PRODUCT INFORMATION LEAFLET

Packaging Leaflet: Information for the User

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

Please read this leaflet carefully before you start using your medicine, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If a side effect occurs and it seems serious to you, or if you notice a side effect not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:

1. What Ultra Chloraseptic® Throat Spray is and what it is used for
2. Before you use Ultra Chloraseptic® Throat Spray
3. How to use Ultra Chloraseptic® Throat Spray
4. Possible side effects
5. How to store your medicine
6. Further information

### 1. What Ultra Chloraseptic® Throat Spray is and what it is used for

Ultra Chloraseptic® Pain Relief Throat Spray 0.71%w/v Oromucosal Spray is used to relieve sore throat pain, and will be referred to as Ultra Chloraseptic® Throat Spray throughout this leaflet.

The product contains the active ingredient benzocaine which belongs to the group of medicines called local anaesthetics. It has a fast action and works by numbing the pain of a sore throat. The product comes in the form of a spray. It has a swivel head applicator to help deliver the local anaesthetic direct to the throat.

### 2. Before you use Ultra Chloraseptic® Throat Spray

DO NOT use this spray if

- you have difficulty in breathing, noisy breathing or severe difficulty in swallowing. Talk to your pharmacist or doctor if this applies to you
- you know you are allergic to benzocaine or any of the other ingredients (see Section 6, Further Information)
- you have been told that you have a rare blood condition called methaemoglobinaemia
- you are pregnant or breast-feeding

DO NOT use this medicine for children under 6 years of age.

This medicine contains a small quantity of alcohol (less than 0.006 units per spray) to dissolve the other ingredients. Contains propylene glycol - this may cause skin irritation.

If your sore throat is severe or prolonged, or accompanied by fever, headache, or feeling sick, consult a doctor.

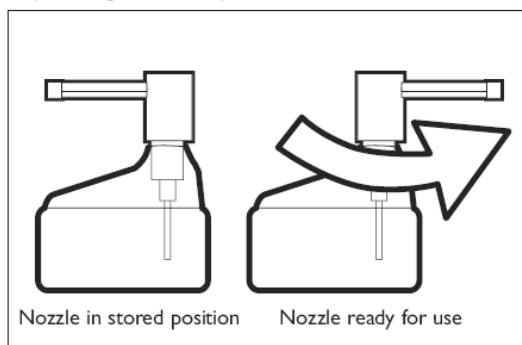
### 3. How to use Ultra Chloraseptic® Throat Spray

Ultra Chloraseptic® Throat Spray is for use by adults and teenagers, and in children aged from 6 years when supervised by an adult.

The product is designed so that the medication can be sprayed directly to the back of the throat.

**The following instructions will help you to get the best results from your spray:**

- Remove the cap from the bottle, and **rotate the spray head around** by half a circle so that the nozzle extends beyond the bottle (see diagram below).

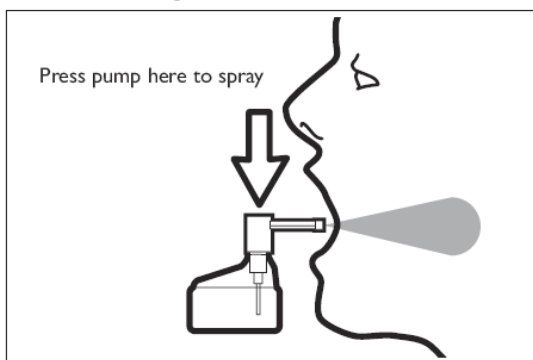


- If this is a new bottle, or you have not used it since your last sore throat, **activate the pump by spraying 3 times away from your face into a sink.** This will also help you to get a feel for the pump action.
- Hold the bottle in your hand with your index (first) finger on the pump, ready to spray.

Continued overleaf

### 3. How to use (CONTINUED)

- When you are ready, open your mouth a little and **point the spray nozzle towards the back of your throat**. The nozzle should be just inside your mouth (see diagram below). This will help the spray get to its target at the back of the throat.
- **Hold your breath and then press the pump to spray**. Do not exceed the dosage on the labelling.



- It may be easier the first few times to stand in front of the mirror whilst spraying the product.

#### Spray Dosage:

DO NOT spray into the eyes. If you accidentally spray into your eyes, rinse them thoroughly under water.

#### For Adults and Teenagers:

- Hold breath and spray 3 times to the back of your throat.
- Repeat every 2-3 hours if required.
- Do not use more than 8 times a day.

#### For Children 6-12 years:

- Use only under adult supervision.
- Do not use in a child who is unable to hold their breath whilst spraying.
- Hold breath and spray once to the back of the throat.
- Repeat every 2-3 hours if required.
- Do not use more than 8 times a day.

DO NOT use for more than 3 days in a row. If symptoms do not improve, consult your pharmacist or 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.**

If you spray more than you should, and you feel drowsy, you must contact a doctor immediately.

### 4. Possible side effects

Allergic reactions have been reported occasionally with benzocaine. Although very unlikely, if your breathing is affected after using the spray, or if your face or mouth become swollen, stop using the spray and seek immediate medical advice.

Methaemoglobinaemia (a very rare blood condition) has been reported with benzocaine use.

If you experience any side effect whilst taking this medicine, tell your doctor or pharmacist.

### 5. How to store your medicine

**Keep out of the reach and sight of children.**

Do not use the spray after the Expiry date which is shown on the top of the carton and on the base of the spray bottle.

### 6. Further information

#### What Ultra Chloraseptic® Pain Relief Throat Spray 0.71%w/v Oromucosal Spray contains

The spray contains Benzocaine 0.71% w/v (1mg per spray) as the active ingredient. It also contains: ethanol, macrogol 300, propylene glycol, glycerol, cetylpyridinium chloride, saccharin sodium, sodium dihydrogen phosphate dihydrate, sodium hydroxide, flavouring (levomenthol) and purified water.

#### What Ultra Chloraseptic® Pain Relief Throat Spray 0.71%w/v Oromucosal Spray looks like and contents of pack

The spray is a clear colourless to straw coloured solution, presented in a glass bottle with a spray nozzle under a plastic cap. Each bottle contains 15ml. The nozzle is used to target the spray to the back of the throat.

The marketing authorisation for Ultra Chloraseptic® Pain Relief Throat Spray 0.71%w/v Oromucosal Spray is held by: Prestige Brands (UK) Limited, 3 Scotlands Drive, Farnham Common, Slough, Berkshire SL2 3ES, UK.

The product is manufactured at: Wagener & Co GmbH, Poststrasse 24, 49525 Lengerich, Germany.

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This leaflet is dated June 2011.

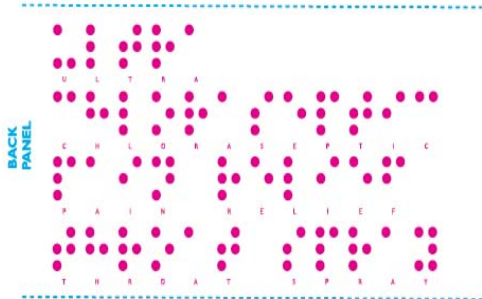
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® Chloraseptic is a registered trademark.

To get this leaflet in large print, Braille or as an audio CD, call the RNIB Medicine Leaflet line on **0800 198 5000** and quote **PL 18259-0005**.

# LABELLING

**Carton:**



**ULTRA  
 CHLORASEPTIC  
 PAIN RELIEF  
 THROAT SPRAY**

Bottle:

**Menthol Flavour**

**Ultra Chloraseptic®**  
**Pain Relief**  
**Throat Spray**

0.71% w/v Oromucosal Spray  
Benzocaine

For the relief of **SORE THROAT** pain.



For optimum use turn the nozzle 180°

**DIRECTIONS:** 00000000  
(Read the enclosed leaflet first before using)  
Adults and Teenagers: Hold breath. Spray 3 times to back of throat. Repeat every 2-3 hours. Do not use more than 8 times a day.  
Child (6-12 years): See leaflet for directions. Use only under adult supervision.

**Warning: Do not exceed the stated dose.**

**CAUTION**  
Do not use on children under 6 years old. Do not use and consult your doctor if you have difficulty in breathing, noisy breathing, or severe difficulty in swallowing. Do not use if you are pregnant or breast-feeding. Do not use if you are allergic to benzocaine or any of the other ingredients or if you have been told you have a rare blood condition called methaemoglobinaemia. Do not use for more than three days in a row. If sore throat is severe or persistent, or accompanied by fever, headache or feeling sick, consult your doctor. Keep out of the reach and sight of children. Do not spray into eyes.

**Active Ingredient:** Benzocaine 0.71% w/v (1 mg per spray).  
Also contains: ethanol, macrogol 300, propylene glycol, glycerol, cetylpyridinium chloride, saccharin sodium, sodium dihydrogen phosphate dihydrate, sodium hydroxide, flavouring (levomenthol), purified water.

PL 18259/0005 Prestige Brands (UK) Limited  
xxxxxxx 3 Scotlands Drive,  
15ml e Farnham Common, Slough,  
Berkshire SL2 3ES, UK.