Patient Leaflet: Information for User

Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray (Benzocaine)

Please read all of this leaflet carefully before you start using this medicine, as it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray is and what it is used for
2. What you need to know before you use Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray
3. How to use Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray
4. Possible side effects
5. How to store Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray
6. Contents of the pack and other information

1. What Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray is and what it is used for

Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray is used to relieve sore throat pain and will be referred to as Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal 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. What you need to know before you use Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal 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)
- you have been told that you have a rare blood condition called methaemoglobinaemia
- you are pregnant or breast-feeding

Warnings and precautions:

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

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

Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray contains alcohol and propylene glycol

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.

3. How to use Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray

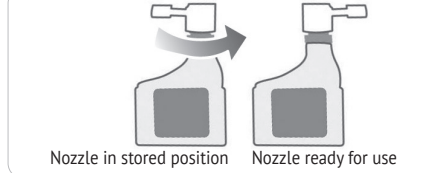
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray is for use by adults and teenagers, and 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).

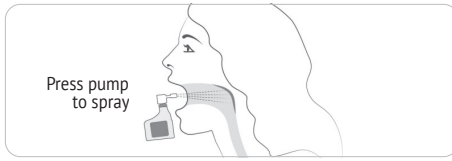


- If this is a new bottle, or you have not used it since your last sore throat, **activate the pump by spraying 3 times away from your face into a sink.** This will also help you to get a feel for the pump action.

Continued overleaf

3. How to use (CONTINUED)

- Hold the bottle in your hand with your index (first) finger on the pump, ready to spray.
- When you are ready, open the 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.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ultra Chloraseptic® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray

Keep out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

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. Contents of the pack and other information

What Ultra Chloraseptic® Sore Throat Pain Relief 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, flavourings (levomenthol) and purified water.

What Ultra Chloraseptic® Sore Throat Pain Relief 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® Sore Throat Pain Relief 0.71% w/v Oromucosal Spray is held by: Prestige Brands (UK) Ltd, 5-7 London Road, St. Albans, AL1 1LA, United Kingdom.

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

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