SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Manx Healthcare Sore Throat Relief Spray 1.5mg Oromucosal Spray
Numark Sore Throat Relief Spray 1.5mg Oromucosal Spray
LloydsPharmacy Sore Throat Relief Spray 1.5mg Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 1.5 mg per actuation. For excipients please 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 2 sprays (3 mg) to the back of the throat. Repeat every two to three hours up to a maximum of 8 doses per day.

This product is contraindicated in children 12 years and under.

Method of administration: oromucosal

Hold breath and spray to the back of the throat.

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

Before first use or after prolonged storage press the plunger 2 – 3 times to activate the spray. Do this away from the face, into a sink.

Instructions for use of Manx Healthcare Sore Throat Relief Spray 1.5 mg Oromucosal Spray

Fig. 1
Resting position (cannot be activated)

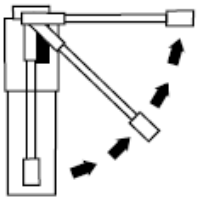
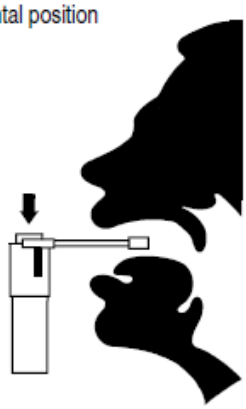


Fig. 2
Raise nozzle from vertical to horizontal position

Fig. 3
Hold your head upright and insert the nozzle well into your mouth. Hold your breath and press the plunger once to deliver a single metered spray.



Pressing the plunger once delivers a single metered spray.

4.3 Contraindications

Children 12 years and under

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 12 years and under

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 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.

This medicine contains less than 1 mmol sodium (23 mg) per actuation, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

None known

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 Manx Healthcare Sore Throat Relief Spray 1.5mg Oromucosal Spray is not recommended during pregnancy or breast feeding.

4.7 Effects on ability to drive and use machines

None.

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 at: 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 should 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

Pharmacotherapeutic group: Anaesthetics, local, ATC code: R02 AD01

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 on the 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 Manx Healthcare Sore Throat Relief Spray 1.5mg Oromucosal Spray has not been tested for duration of action.

5.2 Pharmacokinetic properties

Benzocaine is absorbed into the mucus 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 amoniohippuric 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 Manx Healthcare Sore Throat Relief Spray
1.5 mg Oromucosal Spray Non-clinical studies on benzocaine showed local irritation and sensitisation, and methaemoglobinaemia at high doses in some species.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetylpyridinium chloride
Glycerin,
Ethanol
Clove bud oil
Levomenthol
Sodium saccharin
Peppermint
Cremophor RH40
Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White aluminium spray container with metering pump and high density polyethylene cap, and polypropylene and nitrilic rubber nozzle.

Pack size: not less than 7.3 g (approximately 60 metered doses).

6.6 Special precautions for disposal

To help protect the environment, do not dispose of this medicine via wastewater or household waste. Ask a pharmacist for advice on disposal.

7 MARKETING AUTHORISATION HOLDER

Tillomed Laboratories Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 11311/0788

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24/03/2009

10 DATE OF REVISION OF THE TEXT

09/01/2026