

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

AAA Sore Throat Spray 1.5 mg Oromucosal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzocaine 1.5mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal spray.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic temporary relief of pain associated with sore throat pain and minor infections.

4.2 Posology and method of administration

Adults (including the elderly) and children from 13 years:

Spray two metered doses every two to three hours if required (not more than sixteen doses in every 24 hours) or as directed by the physician.

Children:

Children 6 – 12 years: One metered dose every two to three hours if required (not more than eight doses in every 24 hours) or as directed by the physician.

Not suitable for children under 6 years.

Route of administration

Topical application to the mucosa of the mouth and throat by means of a metered dose aerosol.

Can be shaken before use.

4.3 Contraindications

Known hypersensitivity to benzocaine or any of the other ingredients

Methaemoglobinaemia

Children under 6 years

Epiglottitis

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 methaemoglobaemia.

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 AAA Sore Throat 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.

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.

Treatment of overdose

N/A.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R02A D01

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 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 AAA Sore Throat 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 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 AAA Sore Throat 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, menthol crystals, sodium saccharin 450, peppermint Cremophor, water.

6.2 Incompatibilities

None.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

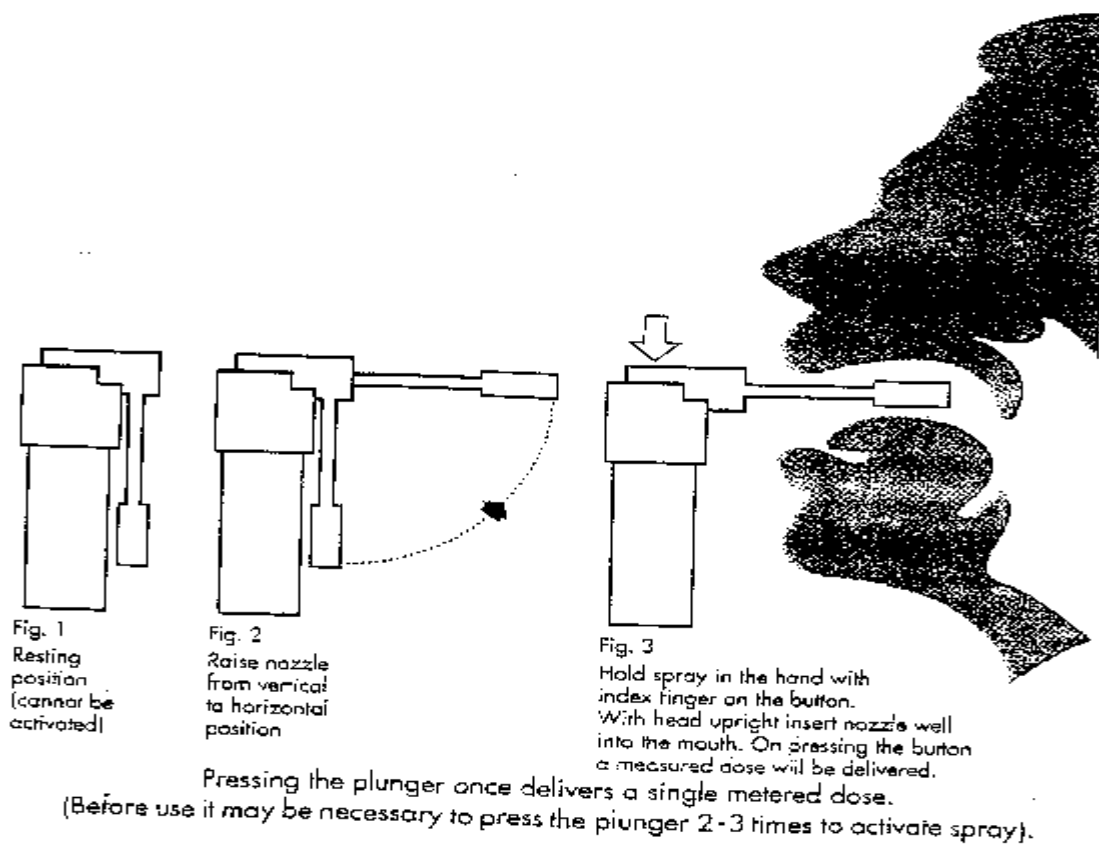
Keep away from naked flame.

Store in a cool place.

6.5 Nature and contents of container

White aluminium can with 100ml pumps, white high density polyethylene folding arm activator and white high density polyethylene cap.

6.6 Special precautions for disposal



7 MARKETING AUTHORISATION HOLDER

Sterling Pharmaceuticals Ltd
288 Upper Balsall Heath Road
Moseley, Birmingham
B12 9DR

8 MARKETING AUTHORISATION NUMBER(S)

PL32515/0056

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st September 1997/2nd January 2007

10 DATE OF REVISION OF THE TEXT

19/07/2023