Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Sore Throat Relief Mint Flavour 8 mg Compressed Lozenge

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each compressed lozenge contains 8 mg of benzocaine.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Compressed Lozenge (Lozenge)
Oval, white to slightly yellow/beige lozenge with a size of about 14 mm x 9 mm x 6 mm, with debossed arrows on one side and the text "B 8" on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicine is indicated for the short-term symptomatic relief of pain and discomfort in acute sore throat. It is indicated in adults and adolescents 16 years and over.

4.2 Posology and method of administration

AdultsandChildren16yearsand over:

1 lozenge to be dissolved slowly in the mouth no more frequently than every two hours.
Do not exceed 6 lozenges in 24 hours.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Do not use for more than 3 days without seeking prior medical advice.

Children under 16 years

For use in adults and adolescents 16 years and over. Do not use in children under 16 years

4.3 Contraindications

This medicine must not be used in children aged less than 16 years.

Hypersensitivity to benzocaine or to any of the excipients listed in section 6.1

In patients who have a history of or are suspected to have methaemoglobinaemia.

4.4 Special warnings and precautions for use

Due to the local anesthetic action of benzocaine patients should avoid eating or drinking directly after taking a lozenge.
Benzocaine may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. Patients should stop use and seek immediate medical attention if they develop pale, grey or blue colored skin, lips, and nail beds, headache, light headedness, shortness of breath, fatigue, or tachycardia.
Use with caution in individuals with aspiration and swallowing problems.
This product is not recommended for use in children under 16 years (see sections 4.1 and 4.2).

4.5 Interaction with other medicinal products and other forms of interactions

No known clinically-relevant drug interactions for benzocaine have been reported.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate and well-controlled studies of benzocaine in pregnant women. This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus.

Breast-feeding
There are no adequate and well-controlled studies of benzocaine in lactating women. It is not known whether benzocaine or its metabolites are excreted in breast milk. This product should not be used during lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the nursing infant.

Fertility
There are no studies on fertility.

4.7 Effects on ability to drive and use machines

It is not known if this medicine has an effect on the ability to drive and use machines.

4.8 Undesirable effects

The undesirable effects have been identified through a review of the literature and reported spontaneously during post-marketing use. Due to limited clinical trial data, a frequency cannot be estimated from the available data and is therefore classified as "not known".
The following side effects may be associated with the use of benzocaine.
The adverse effects listed below are classified by system organ class and frequency according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000) or very rare (<1/10,000).

SOC	Frequency Category	Adverse Event Term
Immune System Disorders	Not Known	Hypersensitivity
Blood and Lymphatic System Disorders	Not Known	Methemoglobinemia
Skin and Subcutaneous Tissue Disorders	Not Known	Rash

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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

From a review of literature of Benzocaine containing products an overdose of Benzocaine may lead to methemoglobinemia, a rare, but serious condition resulting from a decreased amount of oxygen in the blood. Symptoms may include pale, grey or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness and tachycardia. In the most severe cases, methemoglobinemia can result in apnoea, seizures, atrial fibrillation, tachyarrhythmia, hypotension, and death.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anesthetic, ATC code: R02AD01

Mechanism of action

Benzocaine is an anaesthetic belonging to the esters of para-aminobenzoic acid lacking a terminal amino group, is a prototype ester local anaesthetic. The local anaesthetic works by blocking the permeability of sodium ions to the neuronal membrane, thus stabilizing the electric potential of the neuron. Stabilizing the neuron effectively blocks the initiation and conduction of nerve impulses and leads to 'numbing' of the affected area.

The topical anaesthetic effect of benzocaine has been reported to start within 5 to 15 minutes. The duration of action lasts up to 2 hours. In a randomised, double-blind, placebo-controlled trial in 260 subjects with sore throat, benzocaine 8 mg lozenges provided meaningful pain relief compared to placebo ($p<0.001$). Subject questionnaires confirmed the lozenges reduced subjects' difficulty in swallowing within 5 minutes and for up to 2 hours ($p\leq0.009$ vs placebo). When assessed 2 hours after the initial dose, the lozenges had improved the sore throat condition in 117 of 128 subjects (91%) and reduced difficulty in speaking ($p<0.001$ vs placebo).

5.2 Pharmacokinetic properties

ABSORPTION
Benzocaine is well absorbed from mucous membranes but poorly absorbed through intact skin.

DISTRIBUTION
There is no information available regarding the distribution of benzocaine in humans.

BIOTRANSFORMATION
Benzocaine is metabolized in the liver by hepatic and plasma cholinesterase.

ELIMINATION
Benzocaine and its main metabolite, para-aminobenzoic acid, are mainly excreted in the urine. A small amount of benzocaine is excreted unchanged by the kidneys.

5.3 Preclinical safety data

Methemoglobinemia has been reported in various animal species. Benzocaine was non-genotoxic in *in vitro* and *in vivo* assays. There is no other relevant information additional to that contained elsewhere in the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lozenge Core:
Mannitol (E 421)
Magnesium Stearate
Xanthan Gum (E 415)
Macrogol 6000 (E 1521)
Winterfresh Spray dried (containing gum arabic (E414), peppermint, menthol and eucalyptol flavourings)
Sucralose (E 955)
Acesulfame Potassium (E 950)

Film coating:
Hypromellose
Titanium dioxide (E 171)
Winterfresh liquid (containing peppermint, menthol and eucalyptol flavourings)
Macrogol 400 (E 1521)
Sucralose (E 955)
Acesulfame Potassium (E 950)
Polysorbate 80 (E 433)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

The container closure system is a blue Polypropylene container with silica gel.
Twenty lozenges are filled into each container.

Pack Sizes:
20 (1x20)

6.6 Special precautions for disposal

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/058/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2022

10 DATE OF REVISION OF THE TEXT