Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Boots Pharmaceuticals Sore Throat Relief Lemon Flavour 0.6 mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol 0.6 mg per lozenge
Excipients: Sucrose 1.50g
Glucose 1g

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge
Yellow, circular lozenges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the short-term symptomatic relief of sore throats.

4.2 Posology and method of administration

Adults and Children over 12 years: One lozenge to be sucked when required, up to a maximum of 8 lozenges in 24 hours.
Children 5-12 years: One lozenge to be sucked when required up to a maximum of 4 lozenges in 24 hours.
The maximum dose at any one time is one lozenge.
Children under 5 years: Not suitable.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep all medicines out of the reach of children.
Do not exceed the stated dose.
If symptoms persist or worsen after 2-3 days see your doctor.

Information related specifically to the excipients in this formulation (See Section 6.1).
Glucose: Each lozenge contains 1g glucose. This should be taken into account by patients with diabetes mellitus. Patients with rare glucose-galactose malabsorption should not take this medicine.

Sucrose: Each lozenge contains 1.5g sucrose. This should be taken into account by patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are known.

4.6 Fertility, pregnancy and lactation

The safety of Antiseptic Throat Lozenges Lemon has not been established during pregnancy and lactation, but the product is not expected to constitute a hazard during these periods. As with all drugs try to avoid taking them during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

No adverse effects are known.

4.8 Undesirable effects

Occasional hypersensitivity reactions and soreness of the tongue are a possibility.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic. In cases of severe overdosage empty the stomach by gastric lavage. Administer a saline laxative and activated charcoal by mouth.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Amylmetacresol has antiseptic properties.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Terpeneless lemon oil
Star Anise oil
Levomenthol
Glucose

Sucrose
Malic acid
Betacarotene 1%

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

A card carton, containing two push through PVC/PVDC blister trays heat sealed to hard tempered aluminium foil. Pack size: 24 lozenges.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 4/57/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 May 2001

Date of last renewal: 17 May 2006

10 DATE OF REVISION OF THE TEXT

July 2015