SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Anaesthetic & Antibiotic Throat Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Active ingredient</th>
<th>Quantitative Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tyrothricin</td>
<td>1.0 mg/lozenge</td>
</tr>
<tr>
<td>Benzocaine</td>
<td>5.0 mg/lozenge</td>
</tr>
</tbody>
</table>

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of sore throats.

For oral administration.

4.2 Posology and method of administration

Adults and children over 12 years: one lozenge to be sucked slowly as required. Not more than eight lozenges to be taken in any one day.

Children under 12 years: not suitable for children under 12 years.

Elderly: The normal adult dose is still appropriate in the elderly.

4.3 Contraindications

Hypersensitivity to ester type local anaesthetics or the antibiotic tyrothricin, or any of the other ingredients.

Current or past history of methaemoglobinemia
4.4 Special warnings and precautions for use

This product should be used with caution in patients with myasthenia gravis, patients with low plasma cholinesterase concentrations or in those receiving anticholinesterases.

If symptoms persist consult your doctor.

Warning: do no exceed the stated dose.

Keep all medicines out of the reach of children.

4.5. Interactions with other medicinal products and other forms of interaction

These lozenges may interfere with the action of sulphonamides.

4.6 Pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established. As local anaesthetics can cross the placenta, it is recommended that this product is not taken during pregnancy.

No information on the use of this product in lactation is available and it is recommended that this product is not taken whilst breast feeding.

4.7. Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Occasional hypersensitivity reaction and soreness of the tongue. Methaemoglobinaemia can rarely occur.

**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.

4.9 Overdose

Overdosage with this product will produce excessive anaesthesia in the upper alimentary tract. Treatment should be symptomatic and supportive. Gastric lavage and emesis may be required.

In severe overdosage, methaemoglobinaemia may occur. Risk is related to dose and is increased in patients with hereditary methaemoglobinaemia and when used with other oxidising agents. Methaemoglobinaemia may be treated by intravenous administration of 1% solution of methylene blue in a dose of 1-4 mg per kg of bodyweight.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Tyrothricin is an antibiotic. It is a mixture consisting of gramicidin and tyrocidine, both components being mixtures of polypeptides. It is active against many gram positive bacteria.

Benzocaine is a local anaesthetic of the ester type, used exclusively for surface anaesthesia.

5.2. Pharmacokinetic properties

Not applicable

5.3. Preclinical safety data

Not applicable.
6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sodium Chloride
Icing sugar
Ethanol 96%
Acacia powder
Purified water
Clove leaf oil
Star anise Oil
Isopropyl alcohol
Magnesium stearate
Carmine extract OF63

6.2. Incompatibilities
Not applicable

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
A push-through blister pack consisting of a clear PVC blister beat sealed to aluminium foil, each carton contains 24 lozenges contained in a cardboard carton.

6.6. Instructions for use and handling
Not applicable.

7. MARKETING AUTHORISATION HOLDER
The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

8. MARKETING AUTHORISATION NUMBER

PL 0014/5172R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 November 1990

10 DATE OF REVISION OF THE TEXT

19/07/2016