

1. NAME OF THE MEDICINAL PRODUCT

Boots Sore Throat Relief Honey & Lemon Flavour 0.6 mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol BP 0.6 mg per Lozenge

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge

Clear, yellow lozenge.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of sore throat and coughs

4.2 Posology and method of administration

Posology

Adults, the Elderly, and Children aged 3 years and over :-

Suck one lozenge slowly as required.

Do not take more than 12 lozenges in 24 hours.

Not to be given to children under 3 years.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Not to be given to children under 3 years.

Contains a total of 2.4g of sucrose and glucose per lozenge. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no or inadequate evidence of the safety of the active ingredients in this medicine in human pregnancy. The potential risk for humans is unknown.

In the absence of sufficient data, the use during pregnancy is not recommended.

Breast-feeding

It is not known whether the active ingredients of this product are excreted in human breast milk.

In the absence of sufficient data, the use during lactation is not recommended.

Fertility

Studies of the effects on fertility have not been investigated.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following adverse events have been reported during post-marketing experience with amylmetacresol-containing products:

Immune system disorders

Frequency unknown – Hypersensitivity

Gastrointestinal disorders

Frequency unknown – Glossodynia

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

Theoretically symptoms are possible in children if at least 50 lozenges (more than 4 packs) are consumed in a short space of time. In such extreme overdosage, related to menthol ingestion, symptoms may include nausea and vomiting, diarrhoea, profuse sweating and intense thirst.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R02 AA20

Amylmetacresol is an antiseptic.

The product base has a demulcent action.

5.2 Pharmacokinetic properties

Pharmacokinetic considerations do not arise since the pharmacological action is local to the oro-pharyngeal cavity and the constituents are systemically innocuous in the concentrations used.

5.3 Preclinical safety data

None available specific to the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Liquid Glucose

Tartaric Acid

Menthol, Laevo
Lemon Flavour
Honey Flavour 510167E
Beta-carotene E160a

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months for the unopened pack

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package.

6.5 Nature and contents of container

Blister sizes: 8 and 12 lozenges.

Individual blisters of 250micron PVC coated 60gsm PVDC, lidded with HT aluminium foil of 20 micron. Packs sizes: 12 (1x12), 16 (2x 8), 24 (2x12), 36 (3x12) lozenges.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ernest Jackson & Co. Ltd.

High Street,

Crediton

Devon,

EX17 3AP

UK

8 MARKETING AUTHORISATION NUMBER(S)

PL0094/0256

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

17/02/2017

10 DATE OF REVISION OF THE TEXT

16/08/2019