

1. NAME OF THE MEDICINAL PRODUCT

Boots Triple Action Sore Throat Relief Blackcurrant Flavour 2.4 mg Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hexylresorcinol B.P. 2.4mg per lozenge

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge

Round, purple lozenges

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As an antiseptic, demulcent and local anaesthetic for the relief of sore throat and its associated pain.

4.2 Posology and method of administration

Posology

Adults, the Elderly, and Children aged 6 years and over:- One lozenge dissolved slowly in the mouth every three hours or as required. Do not take more than 12 lozenges in 24 hours.

Not to be given to children under 6 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 6 years.

Contains a total of 2.4g of sucrose and liquid glucose solids 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

Reports of hypersensitivity reaction, including rash, urticaria and angioedema, are extremely rare. There have been very rare reports of tongue soreness.

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

Hexylresorcinol overdose may cause minor gastro-intestinal irritation. Treatment would be withdrawal of the product and symptomatic measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: R02 AA12

Hexylresorcinol is a local anaesthetic for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated.

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.

5.3 Preclinical safety data

None available specific to the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Liquid Glucose
Citric Acid Monohydrate
Menthol
Propylene Glycol
Blackcurrant Flavour L-141148
Ponceau 4R E124
Brilliant Black E151

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25°C. Store in the original packaging.

6.5 Nature and contents of container

Blister packs of 250µm PVC coated 60g/m² PVDC with 20µm hard temper aluminium foil packed in a carton or flow wrapped flexible laminate pack.

Pack sizes: 8 (1x8), 12 (1x12) 16 (2x8), 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)

PL 00094/0255

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/03/2017

10 DATE OF REVISION OF THE TEXT

08/10/2019