

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Boots Sore Throat Relief Double Action 2.4 mg Lozenges Cherry Flavour
Tesco Dual Action Cherry Flavour 2.4mg Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hexylresorcinol 2.4 mg per lozenge

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge.

Clear, red 3/4" diameter, round, biconvex, brittle lozenge with a glossy surface.

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

For adults and children aged 6 years and over:

One lozenge dissolved slowly in the mouth every 3 hours or as required.

Do not take more than 12 lozenges in 24 hours.

Paediatric population

Not to be given to children under 6 years.

Elderly

The normal adult dose may be taken.

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 2.4g sucrose and liquid glucose solids per lozenge. Unsuitable in hereditary fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase-isomaltase deficiency.

E122 can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

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

No interaction studies have been performed.

4.6. Fertility, pregnancy and lactation

Pregnancy

There is no or inadequate evidence of the safety of the active ingredient 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 ingredient of this product is 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 gastrointestinal irritation. Treatment would be withdrawal of the product and symptomatic measures as appropriate.

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.

6.1. List of excipients

Menthol

Cherry flavour 500880E

Carmoisine E122

Sucrose

Liquid Glucose

6.2 Incompatibilities

Not applicable.

6.3. Shelf life

36 months

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 strips of 250µm PVC coated 60g/m² PVDC with 20µm hard temper aluminium foil in a carton or laminate flowwrap.

Pack sizes:

6, 8, 10, 12, 16, 24, 30, 32, 36 lozenges.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Ernest Jackson & Co Ltd

High Street

Crediton

Devon

EX17 3AP

UK

8. MARKETING AUTHORISATION NUMBER

PL 00094/0038

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/03/2000

22/10/2009

10 DATE OF REVISION OF THE TEXT

11/03/2019