1 NAME OF THE MEDICINAL PRODUCT

Sainsbury's Healthcare Blackcurrant Flavour Sore Throat 0.6 mg Lozenges
Tesco Health Sore Throat Relief Antiseptic 0.6 mg Lozenges
Wilko Antiseptic Blackcurrant 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

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 Interactions with other Medicaments 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.

5.1. Pharmacodynamic properties

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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-pharangeal cavity and the constituents are systemically innocuous in the concentrations used.

5.3 Preclinical Safety Data

There is no preclinical data available specific to the product.

6.1. List of excipients

Sucrose
Liquid Glucose
Menthol, Leavo
Blackcurrant Flavour 512453E
Tartaric Acid
Brilliant Black E151
Ponceau 4R E124

6.2 Incompatibilities

None.

6.3 Shelf Life

36 months for the unopened pack.

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 strips of 250µm PVC coated 60g PVDC and lidded with 20□hard temper aluminium foil. Packs of 12, 24, 36 or 48 lozenges in a carton.

6.6 Instructions for Use/Handling

None specific to the product/pack

7. MARKETING AUTHORISATION HOLDER

Ernest Jackson & Co. Ltd.
High Street, Crediton
Devon
EX17 3AP
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL00094/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02 December 1998

10 DATE OF REVISION OF THE TEXT

08/04/2021