



Medicines & Healthcare products
Regulatory Agency



Public Assessment Report

UK PAR

**Sore Throat Relief Honey & Lemon Flavour 0.6mg
Lozenges**

(Amylmetacresol)

PL 00094/0256

Ernest Jackson & Company Limited

LAY SUMMARY

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges

(Amylmetacresol)

The product may be referred to as 'Sore Throat Relief Lozenges' in this report.

This is a summary of the Public Assessment Report (PAR) for Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges (PL 00094/0256). It explains how the application for Sore Throat Relief Lozenges was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Sore Throat Relief Lozenges.

For practical information about using Sore Throat Relief Lozenges, patients should read the package leaflet or contact their doctor or pharmacist.

What are Sore Throat Relief Lozenges and what are they used for?

This medicine is the same as Boots Sore Throat Relief 0.6 mg Lozenges Honey & Lemon Flavour (PL 00094/0012; Ernest Jackson & Company Limited, UK), which is already authorised in the UK. Boots Sore Throat Relief 0.6 mg Lozenges Honey & Lemon Flavour will be referred to as 'Boots Sore Throat Lozenges' in the remainder of this Lay Summary. The licence holder (Ernest Jackson & Company Limited, UK) for Boots Sore Throat Relief Lozenges (PL 00094/0012) has agreed that its own scientific data can be used as a basis for the grant of an identical licence for Sore Throat Relief Lozenges (PL 00094/0256; Ernest Jackson & Co. Limited, UK) (informed consent).

Sore Throat Relief Lozenges are recommended for the relief of sore throats and coughs.

How do Sore Throat Relief Lozenges work?

The active substance in Sore Throat Relief Lozenges is amylmetacresol, which has antiseptic properties in a soothing base.

How are Sore Throat Relief Lozenges used?

Sore Throat Relief Lozenges are sucked slowly in the mouth.

Sore Throat Relief Lozenges should always be used exactly as described in the package leaflet. The patient should check with a pharmacist if he/she is not sure.

Dosage

Adults, the elderly and children of 3 years and over:

- One lozenge should be sucked slowly as required.
- The patient should not take more than 12 lozenges in 24 hours.

Sore Throat Relief Lozenges should not be given to children under 3 years.

The patient should not exceed the stated dose.

If symptoms persist, the patient should consult his/her doctor.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

Sore Throat Relief Lozenges can be obtained without a prescription at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

What benefits of Sore Throat Relief Lozenges have been shown in studies?

The application for Sore Throat Relief Lozenges (PL 00094/0256) is considered to be identical to the previously authorised licence for Boots Sore Throat Relief Lozenges (PL 00094/0012; Ernest Jackson & Company Limited, UK), with the same benefits and risks. So, no new studies have been provided for Sore Throat Relief Lozenges (PL 00094/0256). However, reference is made to the studies for Boots Sore Throat Relief Lozenges (PL 00094/0012; Ernest Jackson & Company Limited, UK).

What are the possible side effects from Sore Throat Relief Lozenges?

Like all medicines, Sore Throat Relief Lozenges can cause side effects, although not everybody gets them.

For the full list of all side effects reported with Sore Throat Relief Lozenges, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why are Sore Throat Relief Lozenges approved?

No new or unexpected safety concerns arose from this application. The MHRA, therefore, considered that the benefits of Sore Throat Relief Lozenges outweigh their risks; and the grant of a Marketing Authorisation was recommended.

What measures are being taken to ensure the safe and effective use of Sore Throat Relief Lozenges?

A Risk Management Plan has been developed to ensure that Sore Throat Relief Lozenges are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics (SmPC) and the package leaflet for Sore Throat Relief Lozenges, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously.

Other information about Sore Throat Relief Lozenges

A Marketing Authorisation was granted in the UK to Ernest Jackson & Company Limited on 17 February 2017.

The full PAR for Sore Throat Relief Lozenges follows this summary.

For more information about treatment with Sore Throat Relief Lozenges, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in March 2017.

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges

(Amylmetacresol)

PL 00094/0256

SCIENTIFIC DISCUSSION

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I. INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Ernest Jackson & Co. Limited a Marketing Authorisation for the medicinal product for Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges (PL 00094/0256) on 17 February 2017. This medicine is indicated for the relief of sore throat and coughs and is on the General Sales List (GSL) which means that it is available from both pharmacies and non-pharmacy outlets without prescription.

The product may be referred as 'Sore Throat Relief Honey & Lemon Flavour Lozenges' in this Scientific Discussion.

The application was submitted as a simple abridged (informed consent) application according to Article 10c of Directive 2001/83/EC, as amended. Sore Throat Relief Honey & Lemon Flavour Lozenges (PL 00094/0256) cross-refer to the reference product Boots Sore Throat Relief 0.6 mg Lozenges Honey & Lemon Flavour (PL 00094/0012; Ernest Jackson & Co. Limited, UK), which was authorised on 18 November 1993.

Sore Throat Relief Honey & Lemon Flavour Lozenges contain the active substance, amylmetacresol, which is an antiseptic. The product base has a demulcent action.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of this product.

No new non-clinical or clinical data were submitted or required for this abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, as the data are identical to that of the previously granted cross-reference product.

II. QUALITY ASPECTS

II.1 Introduction

This is an informed consent application for Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges (PL 00094/0256) submitted under Article 10c of Directive 2001/83/EC, as amended.

The application for Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges (PL 00094/0256) cross-refers to Boots Sore Throat Relief 0.6 mg Lozenges Honey & Lemon Flavour (PL 00094/0012; Ernest Jackson & Company Limited, UK), which was authorised in the UK on 18 November 1993. The application is considered valid.

II.2 DRUG SUBSTANCE

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

II.3 MEDICINAL PRODUCT

Name

The proposed name of the product is Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges (PL 00094/0256). The product has been named in line with current requirements.

Strength, pharmaceutical form, route of administration, container and pack sizes

The product is a clear, yellow lozenge. Each lozenge contains 0.6 mg amylmetacresol, as the active substance. The lozenge is sucked in the mouth.

The product is package in individual blisters of 250micron polyvinylchloride coated 60gsm polyvinylidene chloride, lidded with aluminium foil of 20 microns. The product is available in packs sizes of 12 (1x12), 16 (2x 8), 24 (2x12), 36 (3x12) lozenges.

Not all pack sizes may be marketed.

Legal status

The product is available as a General Sale List (GSL) medicine.

Marketing Authorisation Holder/Contact Persons/Company

Ernest Jackson & Company Limited, High Street, Crediton, Devon, EX17 3AP, UK.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a satisfactory CV has been provided.

Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

The manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

TSE Compliance

None of the excipients contains materials of animal or human origin. This is consistent with the cross-reference product.

Control of Finished Product

The proposed finished product specification is in line with the details registered for the cross reference product.

Stability of the Product

The proposed shelf life for the product is 24 months.

The recommended storage condition for the product is ‘Do not store above 25°C. Store in the original package.’

The shelf life/storage conditions are consistent with the details registered for the cross reference product.

Bioequivalence equivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula and utilising the same process as the cross-reference product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

It is recommended that a Marketing Authorisation is granted.

III. NON-CLINICAL ASPECTS

III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of amylmetacresol are well-known, no new non-clinical data are required and none have been provided.

III.2 Pharmacology

No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.3 Pharmacokinetics

No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.4 Toxicology

No new data have been submitted and none are required for this type of application. Refer to Section III.1, Introduction, above.

III.5 Ecotoxicity/Environmental Risk Assessment (ERA)

The Marketing Authorisation Holder has provided suitable justification for not submitting an Environment Risk Assessment (ERA). This is consistent with the cross-reference product.

III.6 Discussion of the non-clinical aspects

The grant of a Marketing Authorisation is recommended.

IV. CLINICAL ASPECTS

IV.1 Introduction

No new clinical data have been submitted and none are required as this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended. As the application is for a product that is essentially identical to the cross-reference product, this is satisfactory.

IV.2 Pharmacokinetics

No new data have been submitted and none are required for this type of application. Refer to Section IV.1, Introduction, above.

IV.3 Pharmacodynamics

No new data have been submitted and none are required for this type of application. Refer to Section IV.1, Introduction, above.

IV.4 Clinical Efficacy

No new data have been submitted and none are required for this type of application. Refer to Section IV.1, Introduction, above.

IV.5 Clinical Safety

No new data have been submitted and none are required for this type of application. Refer to Section IV.1, Introduction, above.

IV.6 Risk Management Plan

The MAH has submitted a Risk Management Plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to this type of application.

A summary of safety concerns is listed in the table below:

Summary of safety concerns	
Important identified risks	Hypersensitivity (rash, urticaria and angioedema) to the active substance or to any of the excipients
Important potential risks	Off-label use in children aged <3 years
Missing information	Use in Pregnancy Excretion in human breast milk and lactation.

Routine pharmacovigilance and routine risk minimisation activities are acceptable to monitor the safety concerns described in the Risk Management Plan.

IV.7 Conclusion

It is recommended that a Marketing Authorisation is granted for Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges, from a clinical point of view.

V. USER CONSULTATION

A final text version of the package leaflet, consistent with the leaflet for the reference product has been provided. The Marketing Authorisation Holder has committed to submitting mock-ups to the relevant regulatory authorities for approval before marketing any pack size. At the same time, the results of readability testing/readability bridging will be submitted to support the proposed leaflet. This proposal is acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

QUALITY

The important quality characteristics of Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

The pharmacodynamics, pharmacokinetics and toxicology of amylmetacresol are well-known. No new non-clinical data were submitted and none are required for this type of application.

CLINICAL EFFICACY

This application is identical to the previously granted application, Boots Sore Throat Relief 0.6 mg Lozenges Honey & Lemon Flavour (PL 00094/0012; Ernest Jackson & Company Limited, UK),

CLINICAL SAFETY

No new data were submitted and none are required for this application. As the safety profile of amylmetacresol is well-known, no additional safety data were required. No new or unexpected safety concerns arose from this application.

PRODUCT LITERATURE

The SmPC, PIL and labelling are satisfactory and in line with current guidance.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with amylmetacresol is considered to have demonstrated the therapeutic value of the compound. The benefit/risk balance is therefore considered to be positive.

RECOMMENDATION

The grant of a Marketing Authorisation is recommended.

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website. The labelling text below is that agreed at the end of the national procedure. The Marketing Authorisation Holder has committed to submit the UK labelling for review to the competent authority before marketing any pack size.

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**Cardboard Carton****1. NAME OF THE MEDICINAL PRODUCT**

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Amylmetacresol 0.6 mg per lozenge

3. LIST OF EXCIPIENTS

Also contains: Sucrose*, liquid glucose*, tartaric acid, honey and lemon flavours, menthol, beta-carotene (E160a).

*Please see enclosed leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

12 lozenges

16 lozenges

24 lozenges

36 lozenges

(nb. Not all pack sizes may be marketed)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Suck one lozenge slowly as required.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

(See section 15 Instructions on Use)

8. EXPIRY DATE

USE BY

9. SPECIAL STORAGE CONDITIONS

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

- Keep out of the sight and reach of children
- Do not take after the use by date (end of the month) printed on the flap

<p>10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</p>

N/A

<p>11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</p>

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

<p>12. MARKETING AUTHORISATION NUMBER(S)</p>

PL 00094/0256

<p>13. BATCH NUMBER</p>

BN

<p>14. GENERAL CLASSIFICATION FOR SUPPLY</p>

GSL

<p>15. INSTRUCTIONS ON USE</p>

Read all of the enclosed leaflet for full instructions.

What this medicine is for

These lozenges are recommended for sore throats and coughs. They contain the active ingredient amylmetacresol which has antiseptic properties in a soothing base.

Before you take this Medicine

- Do not take if you are allergic to any of the ingredients in this medicine
- Do not give to children under 3 years

Talk to your pharmacist or doctor:

- If you are pregnant or breastfeeding

How to take this medicine

Check the foil is not broken before first use. If it is do not take that lozenge.

Adults, the elderly and children over 3 years:

- Suck one lozenge slowly as required.
- Do not take more than 12 lozenges in 24 hours
- Do not give to children under 3 years
- Do not take more than the amount recommended above
- If your symptoms do not go away talk to your doctor

16. INFORMATION IN BRAILLE

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges
(Amylmetacresol)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Ernest Jackson & Co Ltd

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Sore Throat Relief Honey & Lemon Flavour 0.6mg Lozenges

(Amylmetacresol)

PL 00094/0256

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome