Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

UKPAR

LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution
LemoCalm Cold and Flu Relief Powder for Oral Solution

(Paracetamol and phenylephrine hydrochloride)

UK Licence No: PL 17907/0164-0165

Bristol Laboratories Ltd

LAY SUMMARY
LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution
LemoCalm Cold and Flu Relief Powder for Oral Solution
(Paracetamol and phenylephrine hydrochloride)

This is a summary of the public assessment report (PAR) for LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution (PL 179079 0164-0165). It explains how LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution were assessed and their authorisation recommended as well as the conditions of use. It is not intended to provide practical advice on how to use these products.

For practical information about using LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution, patients should read the package leaflets or contact their doctor or pharmacist.

These medicinal products will be referred to as LemoCalm in the remainder of this lay summary for ease of reading.

What is LemoCalm and what is it used for?
These medicines are the same as Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169), which are already authorised. The company that makes Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder, Wockhardt UK Ltd, has agreed that its scientific data can be used as a basis for the grant of identical licences for LemoCalm (Bristol Laboratories Ltd; PL 179079 0164-0165).

LemoCalm is used for the relief of sinus pain, congestion and the symptoms of cold and influenza, including fever, shivers, aches, pains, sore throat and headache.

How does LemoCalm work?
LemoCalm contains the active ingredients paracetamol, which is used to treat pain and reduce temperature, and phenylephrine hydrochloride which is used as a decongestant which helps clear a blocked nose and sinuses to help patients breathe more easily.

How is LemoCalm used?
LemoCalm is available as an oral solution and is taken by mouth.

LemoCalm should always be taken exactly as advised by the patient's doctor.

The usual doses are as follows:

The usual dose in adults, elderly and children over 12 years is one sachet, dissolved in a tumbler of hot (not boiling) water, every 4 hours**.**

LemoCalm should not be given to children under the age of 12.

The dose should not be taken more frequently than every four hours and not more than four times in any 24 hours period. Patients should not exceed the stated dose.

LemoCalm can be obtained without a prescription and is available on the General Sales List (GSL).

For further information on how LemoCalm is used, please see the Summaries of Product Characteristics or the package leaflets available on the MHRA website.

What benefits of LemoCalm have been shown in studies?
The applications for LemoCalm are considered to be identical to the previously authorised licences for Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169), with the same benefits and risks. So, no new studies have been provided for LemoCalm. However, reference is made to the studies for Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169).

What are the possible side effects from LemoCalm?
Like all medicines, LemoCalm can cause side effects, although not everybody gets them.

For the full list of all side effects reported with LemoCalm, see section 4 of the package leaflets.

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

Why is LemoCalm approved?
No new or unexpected safety concerns arose from these applications. The MHRA, therefore, considered that the benefits of LemoCalm outweigh its risks; and the grant of Marketing Authorisations was recommended.

What measures are being taken to ensure the safe and effective use of LemoCalm?
A satisfactory pharmacovigilance system has been provided to monitor the safety of these products.

Other information about LemoCalm
Marketing Authorisations were granted in the UK on 20 December 2005 (PL 17907/0164) and on 14 March 2006 (PL 17907/0165).

The product names, PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution and Primacare Cold and Flu Relief Lemon Powder for Oral Solution, were changed to LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution on 20 January 2016.

The full PAR for LemoCalm follows this summary.

For more information about treatment with LemoCalm, read the package leaflets, or contact your doctor or pharmacist.

This summary was last updated in July 2016.

TABLE OF CONTENTS

I INTRODUCTION

The MHRA granted Bristol Laboratories Limited Marketing Authorisations (licence) for the medicinal products PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution (PL 17907/0164) and Primacare Cold and Flu Relief Lemon Powder for Oral Solution (PL 17907/0165) on 20 of December 2005 and 13 March 2006 respectively. These medicines are used for the relief of the symptoms of colds and influenza, including the relief of aches and pains, sore throat, headache, nasal congestion and lowering of temperature. These products are general sales list (GSL) medicines.

The applications were submitted according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Maximum Flu Strength Hot Lemon Powder and Hot Lemon Cold Relief Powders (PL 00211/0038-0039), which were authorised to The Wallis Laboratory Ltd on 14 July 1998. These reference products underwent change of ownership procedures to the current Marketing Authorisation Holder, Wockhardt UK Limited (PL 29831/0168-0169), on 22 April 2008 and 04 April 2008 respectively.

These medicinal products contain the active ingredients paracetamol, which is used to treat pain and reduce temperature, and phenylephrine hydrochloride which is used as a nasal decongestant.

No new data were submitted nor were they necessary for these simple applications, as the data are identical to those of the previously granted cross-reference products.

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

No new or unexpected safety concerns arose from these simple applications. It was, therefore, judged that the benefits of taking these medicines outweigh the risks. Hence Marketing Authorisations have been granted.

The product names, PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution and Primacare Cold and Flu Relief Lemon Powder for Oral Solution, were changed to LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution on 20 January 2016.

II Quality aspects

II.1 Introduction

These are simple (informed consent) applications for PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution (PL 17907/0164) and Primacare Cold and Flu Relief Lemon Powder for Oral Solution (PL 17907/0165) on 20 of December 2005 and 13 March 2006 respectively submitted under Article 10c of Directive 2001/83/EC, as amended. The applicant has cross-referred to Maximum Flu Strength Hot Lemon Powder and Hot Lemon Cold Relief Powders (PL 00211/0038-0039), which were authorised to The Wallis Laboratory Ltd on 14 July 1998. These reference products underwent change of ownership procedures to the current Marketing Authorisation Holder, Wockhardt UK Limited (PL 29831/0168-0169), on 22 April 2008 and 04 April 2008 respectively. The current applications are considered valid.

II.2. Drug Substances

Drug substance specifications

The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

II.3. Medicinal Product

Name

The proposed product names are PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution and Primacare Cold and Flu Relief Lemon Powder for Oral Solution. The products have been named in line with current requirements.

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

These products are oral solutions and each sachet contains 1000 mg Paracetamol and 10 mg Phenylephrine hydrochloride, as active ingredients. The solution is taken by mouth.

The products are packed in laminate sachets comprising paper / polythene / aluminium foil / polythene. The sachets are packaged in an outer carton, with a Patient Information Leaflet. The pack size is 5 or 10 sachets per carton. Not all pack sizes may be marketed.

The proposed shelf-life (36 months) and storage conditions (do not store above 25°C and store in the original package) are consistent with the details registered for the cross-reference products.

Legal status

On approval, the products will be on the general sales list (GSL).

Marketing Authorisation Holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Bristol Laboratories Limited, Suite 3, 2nd Floor, Congress House, 14 Lyon Road, Harrow, Middlesex, HA1 2EN, United Kingdom.

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

Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference products 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 products.

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

Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference products.

Bioequivalence
No bioequivalence data are required to support these simple abridged applications as the proposed products are manufactured to the same formula utilising the same process as the cross-reference products, Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169).

Expert Report
Satisfactory statements have been provided.

II.4 Discussion on chemical, pharmaceutical and biological aspects

The quality data for these applications are consistent with those approved for Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169) and, as such, have been judged to be satisfactory. The grant of Marketing Authorisations is recommended.

III Non-clinical aspects

As these are abridged simple applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data has been supplied and none are required.

A suitable justification has been provided for not submitting an environmental risk assessment.

The grant of Marketing Authorisations is recommended.

IV Clinical aspects

As these are abridged simple applications submitted under Article 10c of Directive 2001/83/EC, as amended, no new clinical data have been supplied and none are required.

The Marketing Authorisation Holder (MAH) has provided details of a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that they have the services of a qualified person responsible for pharmacovigilance, and have the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Discussion on the clinical aspects
The grant of Marketing Authorisations is recommended for these applications.

V User consultation

The patient information leaflet has been prepared in-line with the details registered for the cross-reference products.

VI Overall conclusion, benefit/risk assessment and recommendation

Quality
The data for these applications is consistent with that previously assessed for the cross-reference products and as such has been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL

Paracetamol and phenylephrine hydrochloride are well known active substances and have been used for the relief of sinus pain and congestion and the symptoms of cold and influenza including headache, sore throat and "feverishness", for many years.

These applications are identical to previously granted applications for Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169).

No new or unexpected safety concerns arose from these applications.

The SmPCs, PILs and labelling are satisfactory and consistent with those for the cross-reference products.

BENEFIT RISK ASSESSMENT

The quality of the products is acceptable and no new non-clinical or clinical concerns have been identified. The applicant's products are identical to the cross-reference products and so interchangeable. Extensive clinical experience with paracetamol and phenylephrine hydrochloride is considered to have demonstrated the therapeutic value of these compounds. The benefit risk assessment is, therefore, considered to be positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) and Patient Information Leaflets (PIL) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The approved labelling for LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution is presented below:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

LemoCalm Cold and Flu Relief Powder for Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each 5g sachet of powder for oral solution contains: Paracetamol Ph. Eur 650mg & Phenylephrine Hydrochloride 10mg.

3. LIST OF EXCIPIENTS

Also contains: Ascorbic Acid 50g (Vitamin C), Sucrose, Aspartame (E951) & Natural Color (E100). The sodium content is 122mg per sachet.
For the relief of: Blocked nose, aches & pains, sore throat, sinus pain & pressure, fever, shivers and headaches. If you are undergoing a course of medical treatment or suffering from liver or kidney disease, consult your doctor before taking these powders.

4. PHARMACEUTICAL FORM AND CONTENTS

5 sachets
10 sachets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.
Please read the enclosed leaflet for further information before use.

Dose: Unless otherwise directed by a doctor-
Adults, the elderly and children over 12 years: One sachet, dissolved in a tumbler of hot (not boiling) water, every 4 hours and not more than 4 times in any 24 hour period.
Maximum dose: 4 Sachets every 24 hours in divided doses.
Children under 12 years: Do not give to children under 12 years of age except on the advice of a doctor. If symptoms persist consult your doctor.

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

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN

7. OTHER SPECIAL WARNING(S), IF NECESSARY

CONTAINS PARACETAMOL. IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSE, EVEN IF YOU FEEL WELL. DO NOT TAKE WITH ANY OTHER PARACETAMOL - CONTAINING PRODUCTS

DO NOT EXCEED THE STATED DOSE.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store below 25°C

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited
Unit 3, Canalside,
Northbridge road,
Berkhamsted HP4 1EG
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

PL 17907/0165

13. BATCH NUMBER

BN:

14. GENERAL CLASSIFICATION FOR SUPPLY

General Sales List

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

SACHET TEXT

FRONT PANEL:

LemoCalm Cold and Flu Relief Powder for Oral Solution

FOR RELIEF OF COLDS & INFLUENZA

•Decongestant

•Pain Reliever

5g sachet

CONTAINS PARACETAMOL AND PHENYLEPHRINE HYDROCHLORIDE

BACK PANEL:

Each 5g sachet of powder for oral solution contains: Paracetamol Ph. Eur 650mg & Phenylephrine Hydrochloride 10mg.
Also contains: Ascorbic Acid 50g (Vitamin C), Sucrose, Aspartame (E951) & Natural Color (E100). The sodium content is 122mg per sachet.

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WARNING: CONTAINS PARACETAMOL. IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF AN OVERDOSE, EVEN IF YOU FEEL WELL. DO NOT TAKE WITH ANY OTHER PARACETAMOL - CONTAINING PRODUCTS

DO NOT EXCEED THE STATED DOSE.

Store below 25°C
If you are undergoing a course of medical treatment or suffering from liver or kidney disease, consult your doctor before taking these powders.

PL 17907/0165
MA Holder
Bristol Laboratories limited

Berkhamsted, Herts, HP4 1EG, UK.

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DO NOT EXCEED THE STATED DOSE.

8. EXPIRY DATE

EXP: MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store below 25°C

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

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FRONT PANEL:

LemoCalm Cold and Flu Relief Powder for Oral Solution

FOR RELIEF OF COLDS & INFLUENZA

•Decongestant

•Pain Reliever

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CONTAINS PARACETAMOL AND PHENYLEPHRINE HYDROCHLORIDE

BACK PANEL:

Each 5g sachet of powder for oral solution contains: Paracetamol Ph. Eur 650mg & Phenylephrine Hydrochloride 10mg.
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PL 17907/0165
MA Holder
Bristol Laboratories limited

Berkhamsted, Herts, HP4 1EG, UK.

BN

EXP

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitment

Date submitted	Application type	Scope	Outcome
22 January 2016	II	To update sections 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.2, 5.3, 6.1, 6.2, 6.3, 6.4, 6.5 and 6.6 of the SmPC in line with the reference SmPC (reference product-Lemsip Max Honey & Ginger Flavour Powder for Oral Solution; PL 00063/0147).	Approved on 23 June 2016

Annex 1

Reference: PL 17907/0164-0035; PL 17907/0165-0035

Product: LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution and LemoCalm Cold and Flu Relief Powder for Oral Solution

Marketing Authorisation Holder: Bristol Laboratories Limited

Active Ingredient: Paracetamol and phenylephrine hydrochloride

Reason:
To update sections 2, 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5.2, 5.3, 6.1, 6.2, 6.3, 6.4, 6.5 and 6.6 of the SmPCs in line with the reference SmPC (reference product-Lemsip Max Honey & Ginger Flavour Powder for Oral Solution; PL 00063/0147).

Supporting evidence
The applicant has submitted updated sections of the SmPCs and PILs.

Evaluation
The amended sections of the SmPCs and PILs are satisfactory.

The applicant was requested to update the SmPCs to be in line with Lemsip Max Honey&Ginger Flavour Powder for Oral solution, to which it refers as the reference product.

From our record it appears that LemoCalm was approved in 2004 as "PrimaCare Maximum Flu Strength Hot Lemon Powder for Oral Solution and Primacare Cold and Flu Relief Lemon Powder for Oral Solution" under Article 10.1(a) as essentially similar to Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 00211/0038-0039), held by The Wallis Laboratory Ltd, granted on 14 July 1998. These reference products underwent change of ownership procedures to the current Marketing Authorisation Holder (MAH), Wockhardt UK Limited (PL 29831/0168-0169), on 22 April 2008 and 04 April 2008 respectively. Therefore, the latter should be considered the Reference product to which the MAH should refer to.

The changes proposed are based on the alignment of the SmPCs for 'LemoCalm Cold and Flu Relief Powder for Oral Solution' and 'LemoCalm Max Strength Cold and Flu Relief Powder for Oral Solution' to be in line with Lemsip Max Honey & Ginger Flavour Powder for Oral Solution.
Other SmPCs were also considered such as: Beechams Breathe Clear Hot Honey & Lemon Menthol Flavour powder for oral solution (for Section 4.8 side effects of phenylephrine) and Paracetamol 500 mg Effervescent Tablets.
To support the inclusion of this extra information, the MAH submitted some literature references.

Conclusion
The changes requested in these variations cannot be approved since the reference product used is incorrect.

Outstanding point

1. From our record, the reference product for LemoCare is not Lemsip but Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder (PL 29831/0168-0169) therefore any changes/update of the SmPCs/PILs should refer to these.

The Applicant sought for advice on how to update their SmPCs and PILs in line with the most up to date safety and pharmacovigilance information since the reference products, Hot Lemon Cold Relief Powders and Maximum Flu Strength Hot Lemon Powder, (PL 00211/0038-0039) were last updated in 2007.

The Applicant was informed that section 4.1 and 4.2 can only refer to the reference products and therefore will not be assessed with these variations. However, an assessment of section 4.3-5.2 was conducted in order to evaluate if important new safety information on products containing paracetamol and phenylephrine were necessary.

The Applicant has implemented the requested changes. Updated sections of the SmPCS and PILs were provided. The proposed SmPCs and PILs are approvable.

Conclusion
The variations were approved on 23 June 2016 and the updated SmPCs fragments and PILs have been incorporated into these Marketing Authorisations. The proposed changes are acceptable.