

**STREPSILS BLACKCURRANT FLAVOUR LOZENGES**

**STREPSILS DRY & SORE THROAT BLACKCURRANT  
FLAVOUR LOZENGES**

**(amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium  
ascorbate)**

**PL 00063/0692**

**UKPAR**

**TABLE OF CONTENTS**

Lay Summary	Page 2
Scientific Discussion	Page 4
Steps Taken for Assessment	Page 12
Steps Taken After Initial Procedure – Summary	Page 13
Summary of Product Characteristics	Page 14
Patient Information Leaflet	Page 15
Labelling	Page 16

**STREPSILS BLACKCURRANT FLAVOUR LOZENGES**  
**STREPSILS DRY & SORE THROAT BLACKCURRANT**  
**FLAVOUR LOZENGES**  
(amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium ascorbate)

**PL 00063/0692**

**LAY SUMMARY**

This is a summary of the Public Assessment Report (PAR) for Strepsils Blackcurrant Flavour Lozenges and Strepsils Dry & Sore Throat Blackcurrant Flavour Lozenges (PL 00063/0692). These medicinal products are identical to each other apart from the difference in product name and will be referred to as Strepsils Blackcurrant Flavour Lozenges in the remainder of this report.

This summary explains how Strepsils Blackcurrant Flavour Lozenges were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Strepsils Blackcurrant Flavour Lozenges.

For practical information about using Strepsils Blackcurrant Flavour Lozenges patients should read the package leaflet or contact their doctor or pharmacist.

**What are Strepsils Blackcurrant Flavour Lozenges and what are they used for?**

The product is a blackcurrant flavoured and coloured circular lozenge containing 0.6mg amylmetacresol, 1.2mg 2,4-dichlorobenzyl alcohol, and ascorbic acid and sodium ascorbate in an amount equivalent to 100.0mg ascorbic acid. Strepsils Blackcurrant Flavour Lozenges are used for the symptomatic relief of mouth and throat infections and provide a source of vitamin C.

**How are Strepsils Blackcurrant Flavour Lozenges used?**

A lozenge should be placed in the mouth and allowed to dissolve slowly every 2-3 hours. Strepsils Blackcurrant Flavour Lozenges can be bought from pharmacies and other outlets.

**How do Strepsils Blackcurrant Flavour Lozenges work?**

The lozenges work by killing the bacteria that are associated with mouth and throat infections. The action of sucking the lozenge allows the active ingredients to work in the area of discomfort and also helps to lubricate and soothe the painful area. Ascorbic acid helps to provide vitamin C, which may be beneficial during infections when vitamin C levels are believed to fall.

**How have Strepsils Blackcurrant Flavour Lozenges been studied?**

This application is identical to the previously granted application for Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat (PL 00063/0391) which were authorised

in the UK to Crookes Healthcare Limited on 14 August 1984 and, following a change of ownership on 19 March 2010, are now authorised to Reckitt Benckiser Healthcare (UK) Ltd. The only difference between the products is in the colour and flavour of the lozenge, which does not affect how the lozenges work.

**What are the benefits and risks of Strepsils Blackcurrant Flavour Lozenges?**

As Strepsils Blackcurrant Flavour Lozenges are considered to be identical to Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat, their benefits and risks are taken as being the same.

**Why are Strepsils Blackcurrant Flavour Lozenges approved?**

No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Strepsils Blackcurrant Flavour 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 Strepsils Blackcurrant Flavour Lozenges?**

A Risk Management Plan has been developed to ensure Strepsils Blackcurrant Flavour Lozenges are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Strepsils Blackcurrant Flavour Lozenges.

**Other information about Strepsils Blackcurrant Flavour Lozenges**

A Marketing Authorisation was granted in the UK on 18 March 2014.

For more information about Strepsils Blackcurrant Flavour Lozenges, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in April 2014.

The full PAR for Strepsils Blackcurrant Flavour Lozenges follows this summary.

**STREPSILS BLACKCURRANT FLAVOUR LOZENGES  
STREPSILS DRY & SORE THROAT BLACKCURRANT  
FLAVOUR LOZENGES  
(amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium  
ascorbate)**

**PL 00063/0692**

**SCIENTIFIC DISCUSSION**

**TABLE OF CONTENTS**

Introduction	Page 5
Pharmaceutical Assessment	Page 6
Non-clinical Assessment	Page 9
Clinical Assessment	Page 10
Overall Conclusion and Benefit/Risk Assessment	Page 11

## **INTRODUCTION**

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Reckitt Benckiser Healthcare (UK) Ltd a Marketing Authorisation for the medicinal product Strepsils Blackcurrant Flavour Lozenges (PL 00063/0692) on 18 March 2014. The product is on the General Sales List (GSL) and is available from pharmacies and other outlets without prescription. Strepsils Blackcurrant Flavour Lozenges are indicated for the symptomatic relief of mouth and throat infections.

This application was submitted as an abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat (PL 00063/0391) which were authorised in the UK to Crookes Healthcare Limited on 14 August 1984. Following a change of ownership on 19 March 2010 Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat are now authorised to Reckitt Benckiser Healthcare (UK) Ltd.

Strepsils Blackcurrant Flavour Lozenges contain the active ingredients amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium ascorbate. Amylmetacresol and 2,4-dichlorobenzyl alcohol have antiseptic properties and ascorbic acid and sodium ascorbate provide a source of vitamin C, which may be beneficial during infection when vitamin C levels are believed to fall.

No new data were submitted nor were necessary for this simple application, as the data are identical to those of the previously granted cross-reference product. Strepsils Blackcurrant Flavour Lozenges are identical to Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat apart from the difference in colour and flavour of the lozenge, which does not affect how the lozenges work.

**PHARMACEUTICAL ASSESSMENT**

<b>LICENCE NO:</b>	PL 00063/0692
<b>PROPRIETARY NAME:</b>	Strepsils Blackcurrant Flavour Lozenges
<b>ACTIVES:</b>	Dichlorobenzyl alcohol Amylmetacresol Ascorbic acid Sodium ascorbate
<b>COMPANY NAME:</b>	Reckitt Benckiser Healthcare (UK) Ltd
<b>E.C. ARTICLE:</b>	Article 10c of Directive 2001/83/EC, as amended
<b>LEGAL STATUS:</b>	GSL

**1. INTRODUCTION**

This is an abridged application for Strepsils Blackcurrant Flavour Lozenges, submitted under Article 10c of Directive 2001/83/EC, as amended.

The application cross-refers to Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat (PL 00063/0391) which were authorised in the UK to Crookes Healthcare Limited on 14 August 1984 and, following a change of ownership on 19 March 2010, are now authorised to Reckitt Benckiser Healthcare (UK) Ltd. The current application is considered valid.

**2. MARKETING AUTHORISATION APPLICATION FORM****2.1 Names**

The proposed names of the product are Strepsils Blackcurrant Flavour Lozenges and Strepsils Dry & Sore Throat Blackcurrant Flavour Lozenges. The product has been named in line with current requirements.

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

The blackcurrant flavoured and coloured circular lozenges contain 0.6mg amylmetacresol, 1.2mg 2,4-dichlorobenzyl alcohol, and ascorbic acid and sodium ascorbate in an amount equivalent to 100.0mg ascorbic acid. The lozenges are used in the mouth.

Strepsils Blackcurrant Flavour Lozenges are packaged in push-through blister packs consisting of hard temper aluminium foil heat-sealed to a PVC/PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 6, 8, 10, 12, 16, 20, 24, 32 and 36 lozenges in a cardboard carton.

**2.3 Legal status**

On approval, the product will be available as a General Sales List (GSL) medicine.

**2.4 Marketing Authorisation Holder**

Reckitt Benckiser Healthcare (UK) Ltd, Slough, SL1 3UH, UK.

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

## **2.5 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.

## **2.6 Qualitative and quantitative composition**

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

## **2.7 Manufacturing process**

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

## **2.8 Finished product/shelf-life specification**

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

## **2.9 Drug substance specification**

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

## **2.10 TSE Compliance**

None of the excipients contain materials of animal or human origin.

## **2.11 Bioequivalence**

No bioequivalence data are required to support this simple abridged application because the proposed product is manufactured to the same formula (apart from differences as a result of the blackcurrant flavour) and utilises the same processes as the reference product Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat.

## **3. EXPERT REPORT**

The applicant cross-refers to the data for Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat, to which this application is claimed to be identical. This is acceptable.

## **4. PRODUCT NAME & APPEARANCE**

See Section 2.1 for details of the proposed product name. The appearance of the product is identical to that of the cross-reference product, apart from the difference in product colour.

## **5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

The proposed Summary of Product Characteristics is consistent with the details registered for the cross-reference product.

## **6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING**

### **PIL**

The Patient Information Leaflet has been prepared in line with the details registered for the cross-reference product.

User testing of the package leaflet for Strepsils Blackcurrant Flavour Lozenges (PL 00063/0692) has been accepted based on the bridging report provided by the applicant making reference to the user-testing of the PIL for Strepsils Orange with Vitamin C 100mg

and Strepsils Dry & Sore Throat, as the 'parent PIL'. As the proposed and reference leaflets are considered the same, no further user testing of the leaflet for this product is considered necessary.

#### Carton and labels

The proposed artwork is consistent with the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging.

### **7. CONCLUSION**

The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.



## **NON-CLINICAL ASSESSMENT**

As this is an abridged application submitted under Article 10c of Directive 2001/83/EC, as amended, no new non-clinical data have been supplied and none are required.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As this product is intended for substitution with a product that is already marketed, no increase in environmental burden is anticipated. Thus, the justification for non-submission of an Environmental Risk Assessment is accepted.

The grant of a Marketing Authorisation is recommended.

## **CLINICAL ASSESSMENT**

As this is an abridged application 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 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.

The Risk Management Plan is considered adequate given that Strepsils Blackcurrant Flavour Lozenges are identical to the innovator product. Routine risk minimisation is provided through the Summaries of Product Characteristics and the Patient information Leaflet and this is sufficient.

The grant of a Marketing Authorisation is recommended.

## **OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT**

### **QUALITY**

The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

### **NON-CLINICAL**

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

### **EFFICACY**

The application is identical to the previously granted application for Strepsils Orange with Vitamin C 100mg and Strepsils Dry & Sore Throat.

### **SAFETY**

No new safety data were supplied or required for this application. Amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium ascorbate have well-established safety profiles. No new or unexpected safety concerns arose from this application.

### **PRODUCT LITERATURE**

The SmPC, PIL and labelling text are satisfactory and consistent with those for the cross-reference product.

### **BENEFIT/RISK ASSESSMENT**

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium ascorbate is considered to have demonstrated the therapeutic value of the product. The benefit/risk balance is therefore considered to be positive.

**STREPSILS BLACKCURRANT FLAVOUR LOZENGES  
STREPSILS DRY & SORE THROAT BLACKCURRANT  
FLAVOUR LOZENGES  
(amylmetacresol, 2,4-dichlorobenzyl alcohol, ascorbic acid and sodium  
ascorbate)**

**PL 00063/0692**

**STEPS TAKEN FOR ASSESSMENT**

- 1 The MHRA received the Marketing Authorisation application on 3 April 2012.
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 24 May 2012.
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 8 August 2012, 20 February 2013 and 24 January 2014.
- 4 The applicant responded to the MHRA's request, providing further information on 15 November 2012, 15 August 2013 and 30 January 2014.
- 5 The application was granted on 18 March 2014.

## **STEPS TAKEN AFTER INITIAL PROCEDURE – SUMMARY**

Not applicable

## **SUMMARY OF PRODUCT CHARACTERISTICS**

In accordance with Directive 2010/84/EU, the Summaries of Product Characteristics (SmPCs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

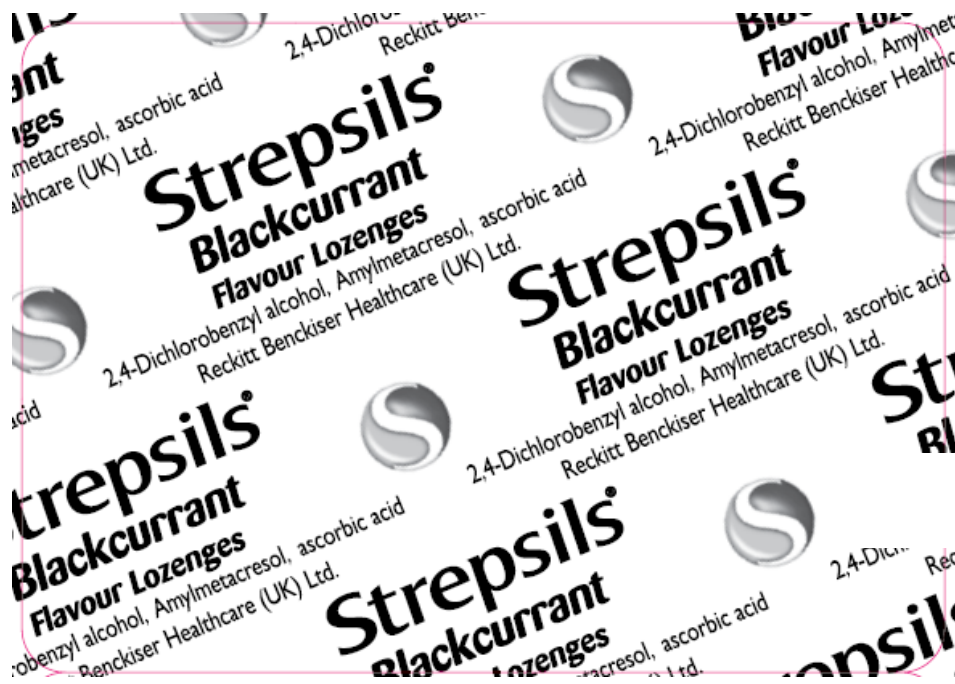
## **PATIENT INFORMATION LEAFLET**

In accordance with Directive 2010/84/EU, the Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

### LABELLING

The following label mock ups are for Strepsils Blackcurrant Flavour Lozenges. No label mock-ups have been provided for Strepsils Dry & Sore Throat Blackcurrant Flavour Lozenges. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained.

**Blister:**





Carton:

Ink & Varnish Free Area

Wording prepared September 2012  
or call us free (UK only) on 0500 455 456  
Hull, HU8 7BR  
Reckitt Benckiser Healthcare (UK) Limited,  
Consumer Information, Freepost HU7831,  
Please write to:  
We welcome your comments and suggestions.  
Licence Holder:  
Reckitt Benckiser Healthcare  
(UK) Ltd, SL1 3UH.  
PL 00063/0692

See insert leaflet for further information.  
Also contains sucrose, glucose.  
0.6mg of Amylmetacresol & 100mg of Ascorbic acid.  
Each lozenge contains 1.2mg of 2,4-Dichlorobenzyl alcohol.  
Do not use after the expiry date.  
If symptoms persist consult your doctor.  
• anything unusual happens  
• you take too many lozenges  
Consult your doctor or pharmacist if:  
• common if you are allergic to aspirin.  
May cause allergic reactions including asthma. This is more  
before taking this product.  
If you have an intolerance to some sugars, contact your doctor  
if you are pregnant, or if you have been told by your doctor that  
product.  
If you are allergic to any of the ingredients do not use this  
Remember young children can choke on lozenges.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.  
Do not store above 25°C.

For oral administration only.  
years old) and the elderly. Not suitable for children under 6 years. Dissolve one lozenge slowly in the mouth every 2 to 3 hours. No more than 12 lozenges per day. Do not exceed the stated dose.  
How to use: Strepsils Blackcurrant Flavour Lozenges are suitable for Adults and Children (over 6 years old) and the elderly. Not suitable for children under 6 years. Dissolve one lozenge slowly in the mouth every 2 to 3 hours. No more than 12 lozenges per day. Do not exceed the stated dose.  
Also contains Vitamin C which may be beneficial during infection when Vitamin C levels are believed to fall.  
the symptomatic relief of mouth and throat infections.  
(2,4-Dichlorobenzyl alcohol & Amylmetacresol) for use in throat medications. These are used for

Strepsils® Blackcurrant Flavour Lozenges contains two antiseptic ingredients

Strepsils®

Blackcurrant Flavour Lozenges

Soothing effective relief for sore throats

Strepsils®

Blackcurrant Flavour Lozenges

2,4-Dichlorobenzyl alcohol,  
Amylmetacresol Ascorbic acid  
*with Vitamin C*

12 lozenges

Do Not Use After:

Lot 1
Lot 2
Lot 3

LOT:

Lot 1
Lot 2
Lot 3

Strepsils®

Blackcurrant Flavour Lozenges

RB004980