Strepsils Children 6+ Lozenges

PL 00063/0650

UKPAR

TABLE OF CONTENTS

STREPSILS CHILDREN 6+ LOZENGES

PL 00063/0650

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Strepsils Children 6+ Lozenges (product licence number: PL 00063/0650) on 14 October 2011. This medicine is available from pharmacies and other outlets without prescription.

Strepsils Children 6+ Lozenges contain two ingredients that are used to relieve the symptoms of mouth and throat infections: amylmetacresol BP and 2,4-dichlorobenzyl alcohol. These ingredients are both mild antiseptics which kill the bacteria associated with mouth and throat infections. The action of sucking the lozenge allows the active ingredients to work in the area of the discomfort and also helps lubricate and soothe the painful area. This helps to relieve the soreness and discomfort of mouth and throat infections.

Strepsils Children 6+ Lozenges raised no clinically significant safety concerns and it was, therefore, judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.

STREPSILS CHILDREN 6+ LOZENGES

PL 00063/0650

SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Strepsils Children 6+ Lozenges to Reckitt Benckiser Healthcare (UK) Ltd on 14 October 2011.

This is an abridged application submitted under Article 10(c) of EC Directive 2001/83, last paragraph. The applicant claims that this product is identical to Strepsils Strawberry Sugar Free Lozenges, which was first licensed to Crookes Healthcare Limited on 28 September 2004 (PL 00327/0165). Following a Change of Ownership on 6 April 2010, Strepsils Strawberry Sugar Free Lozenges is now licensed to Reckitt Benckiser Healthcare (UK) Ltd (PL 00063/0395).

No new data were submitted, nor was it necessary for this simple application, as the data are identical to those for the previously granted cross-reference product.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCES: AMYLMETACRESOL BP
2,4-DICHLOROBENZYL ALCOHOL

The amylmetacresol BP and 2,4-dichlorobenzyl alcohol used in this product are identical to those used in the reference product and are, therefore, satisfactory.

DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

Each lozenge contains 0.6mg amylmetacresol BP and 1.2mg 2,4-dichlorobenzyl alcohol. The lozenges also contain the excipients flav P strawberry flavour, ponceau 4R (E124), saccharin sodium Ph Eur (E954), tartaric acid Ph Eur, isomalt (isomaltitol E953) and maltitol syrup (E965). There is no difference between the composition of the proposed product and that of the already licensed cross reference product.

ADDITIONAL DATA REQUIREMENTS

The manufacturing process, active ingredient specifications and finished product specification are in line with those for the reference product and are satisfactory.

Confirmation is given that none of the lozenge ingredients are of animal origin. The lozenges, therefore, pose no TSE risk.

EXPERT REPORTS

Satisfactory expert reports in the form of quality, non-clinical and clinical overall summaries are provided, with signed declarations from each expert confirming that the applicant's product is identical to the reference product in all particulars. Expert CVs are also submitted and are acceptable.

PRODUCT LITERATURE

All product literature is essentially identical to that for the reference product and is satisfactory.

A Package Leaflet been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the label text is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the label information.

ASSESSOR'S OVERALL CONCLUSIONS

A Marketing Authorisation may be granted for this product.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none is required for an application of this type.

CLINICAL ASSESSMENT

OVERVIEW
A statement has been provided confirming that the clinical particulars for Strepsils Children 6+ Lozenges are identical to those for the already licensed product; Strepsils Strawberry Sugar Free Lozenges (PL 00063/0395). This is satisfactory.

BIOAVAILABILITY AND BIOEQUIVALENCE
No bioequivalence study has been performed to support this application and none is needed.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS
It is recommended that a Marketing Authorisation can be granted.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

Strepsils Children 6+ Lozenges (PL 00063/0650) are identical to the already licensed reference product Strepsils Strawberry Sugar Free Lozenges (PL 00063/0395). This product is, therefore, pharmaceutically satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

The efficacy of amylmetacresol BP and 2,4-dichlorobenzyl alcohol is well established. The product literature is satisfactory and consistent with that for the reference product.

BENEFIT/RISK ASSESSMENT

The quality of the product is acceptable, no significant preclinical or clinical safety concerns were identified, and benefit has been shown to be associated with amylmetacresol BP and 2,4-dichlorobenzyl alcohol. The benefit/risk balance is therefore considered to be acceptable.

STREPSILS CHILDREN 6+ LOZENGES

PL 00063/0650

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the Marketing Authorisation application on 20 December 2010
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 14 February 2011
3	Following assessment of the application the MHRA requested further information relating to the dossier on 22 March 2011
4	The applicant responded to the MHRA's request, providing further information on the dossier on 5 August 2011
5	Following assessment of the response the MHRA requested further information relating to the dossier on 1 September 2011
6	The applicant responded to the MHRA's request, providing further information on the dossier on 16 September 2011
7	The application was determined on 14 October 2011

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Children 6+ Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients
Amylmetacresol BP 0.6mg/lozenge
2,4-Dichlorobenzyl alcohol 1.2mg/lozenge

Excipients
Also contains Ponceau 4R (E124) 0.01mg/lozenge

For full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

A pink coloured circular lozenge with a characteristic taste of strawberries. Strepsils brand icon is intagliated on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an antiseptic for the relief of sore throat and its associated pain.

4.2 Posology and method of administration

For oral administration

Adults and children (over 6 years old)
One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours.

Not suitable for children under 6 years.

Elderly
There is no need for dosage reduction in the elderly

4.3 Contraindications

Strepsils Children 6+ Lozenges are contraindicated in persons who have previously shown hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep all medicines out of the reach and sight of children.

Not to be given to children under 6 years.

If symptoms persist consult your doctor.

Warning: Do not exceed the stated dose.

Consult your doctor if symptoms persist or are accompanied by a high fever or headache.

Contains isomaltitol and maltitol syrup, which may have a mild laxative effect if several are taken a day. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Also Contains Ponceau 4R (E124) which may cause allergic reactions

4.5 Interaction with other medicinal products and other forms of interaction
None known.

4.6 Pregnancy and lactation
The product is not contraindicated during pregnancy and lactation. However, as with all medicines during this period, caution should be exercised.

4.7 Effects on ability to drive and use machines
No adverse effects known.

4.8 Undesirable effects
Occasional hypersensitivity reactions.

4.9 Overdose
In view of the nature and presentation of Strepsils Children 6+ Lozenges, accidental or deliberate overdosage is highly unlikely.

Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
2,4-Dichlorobenzyl alcohol and amylmetacresol have antiseptic properties.

5.2 Pharmacokinetic properties
No data available.

5.3 Preclinical safety data
There are no preclinical data available specific to the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Flav P Strawberry Flavour
Ponceau 4R (E124)

Saccharin sodium Ph Eur (E954)
Tartaric acid Ph Eur
Isomalt (Isomaltitol E953)
Maltitol syrup (E965)

6.2 Incompatibilities
Not applicable

6.3 Shelf life
2 years

6.4 Special precautions for storage
Do not store above 25°C

6.5 Nature and contents of container
The lozenges are contained in a strip pack containing either 6, 8, 12, 16, 20, 24, 32 or 36 lozenges packed into a cardboard carton.

The lozenges are contained in a strip pack containing 8 lozenges packed into a wrap around cardboard carton with tamper-evident seal.

Not all pack sizes may be marketed

6.6 Special precautions for disposal
None

7 MARKETING AUTHORISATION HOLDER
Reckitt Benckiser Healthcare (UK) Ltd
Slough
SL1 3UH

8 MARKETING AUTHORISATION NUMBER(S)
PL 00063/0650

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
14/10/2011

10 DATE OF REVISION OF THE TEXT
14/10/2011

PATIENT INFORMATION LEAFLET

STREPSILS Children 6+ Lozenges
2,4-Dichlorobenzyl alcohol
Amylmetacresol

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Strepsils Children 6+ Lozenges carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT STREPSILS CHILDREN 6+ LOZENGES ARE AND WHAT THEY ARE USED FOR

Strepsils Children 6+ Lozenges contains two antiseptic ingredients for use in throat medications. These are used for the symptomatic relief of mouth and throat infections. These ingredients are both mild antiseptics which kill the bacteria associated with mouth and throat infections. The action of sucking the lozenge allows the active ingredients to work in the area of the discomfort and also helps lubricate and soothe the painful area. This helps relieve the soreness and discomfort of mouth and throat infections.

2. BEFORE YOU TAKE STREPSILS CHILDREN 6+ LOZENGES

This product is recommended for adults, children (over 6 years old) and the elderly.
Children under 6 years old should not use this product.

Do not take this product if you:
- are allergic (hypersensitive) to 2,4-dichlorobenzyl alcohol, amylmetacresol, isomaltitol, maltitol syrup or any of the other ingredients shown in Section 6 – Further Information
- are under 6 years old.

Do not take this product if:
- You have an intolerance to certain sugars such as fructose, glucose-galactose and sucrose-isomaltose. These would be normally confirmed by your doctor. Intolerance would lead from conditions such as deficiency of the enzyme fructose-1-phosphate aldolase (leading to fructose intolerance), glucose-galactose malabsorption and sucrase-isomaltase deficiencies.

Tell your doctor or pharmacist if you:
- are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- suffer or are suffering from any other throat problems

Pregnancy and breast-feeding
It is not recommended to use this product if you think you are pregnant, are pregnant or are breastfeeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients in this product
This product contains isomaltitol and maltitol. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this product.
This product contains Ponceau 4R (E124) which may cause allergic reactions.

3. HOW TO TAKE STREPSILS CHILDREN 6+ LOZENGES

Remove one lozenge from the foil blister packaging.
Replace the foil blister back into the cardboard carton.
Place lozenge into the mouth allowing it to dissolve slowly.

Dissolve one lozenge slowly in the mouth every 2 – 3 hours.

Adults, Children (over 6 years old) and the elderly – One lozenge to be dissolved slowly in the mouth every 2 – 3 hours up to a maximum of 12 lozenges in 24 hours

It is not recommended that children under 6 years use this product.

Remember that young children can choke on lozenges.

If symptoms persist for more than 3 days or if anything unusual happens please consult your doctor.

If you take more of this product than you should
You may experience stomach discomfort
Do not take any more of this product and consult your doctor or pharmacist.

If you forget to take this product
Do not take a double dose to make up for a forgotten lozenge. Continue to use this product normally.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Strepsils Children 6+ Lozenges can cause side effects, although not everybody gets them.
If you experience any hypersensitivity to this product i.e. itching, stop taking this product and consult your doctor or pharmacist.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE STREPSILS CHILDREN 6+ LOZENGES
Keep out of the reach and sight of children.
Do not use this product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month and the year.
Do not store above 25°C
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Strepsils Children 6+ Lozenges Contain
The active substances are:
2,4-Dichlorobenzyl alcohol 1.2mg
Amylmetacresol 0.6mg

The other ingredients are
Strawberry Flavour
Ponceau 4R (E124)
Saccharin sodium (E954)
Tartaric acid
Isomalt (E953)
Maltitol syrup (E965)

What Strepsils Children 6+ Lozenges look like
A pink circular lozenge.

Marketing Authorisation Holder:
Reckitt Benckiser Healthcare (UK) Limited
Slough
SL1 3UH

Manufacturer
Reckitt Benckiser Healthcare International Limited
Nottingham
NG90 2DB

Licence Number: PL 00063/0650
Date of preparation September 2011

RB004490

LABELLING

Blister:

Carton:


Strepsils
Children 6+ Lozenges
Soothing relief for sore throats
Strepsils
Children 6+
Lozenges
2,4-Dichlorobenzyl alcohol,
Amylmetacresol
Strawberry sugar free
24 lozenges
LOT:
Do Not Use After:
Lane 1
Lane 2
Lane 3
FPO
Strepsils
Children 6+ Lozenges
Strepsils® Children 6+ Lozenges contains two antiseptic ingredients (2,4-Dichlorobenzyl alcohol & Amylmetacresol) for use in throat medications. These are used for the symptomatic relief of mouth and throat infections.
Strepsils Children 6+ Lozenges are suitable for use by people with Diabetes.
How to use: Strepsils Children 6+ Lozenges are suitable for Adults and Children (over 6 years old). 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. For oral administration only.
• Remember young children can choke on lozenges.
• If you are allergic to any of the ingredients do not use this product.
• This product contains isomaltitol and maltitol syrup which may have a mild laxative effect if several are taken a day.
• If you are pregnant, or if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product. May cause allergic reactions including asthma. This is more common if you are allergic to aspirin.
• Consult your doctor or pharmacist if:
• you take too many lozenges
• anything unusual happens
• If symptoms persist consult your doctor.
• This product contains Ponceau 4R (E124) which may cause allergic reactions.
• Do not use after the expiry date.
KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Do not store above 25ºC.
Each lozenge contains 1.2mg of 2,4-Dichlorobenzyl alcohol & 0.6mg of Amylmetacresol. Also contains Maltitol syrup and isomaltitol. See insert leaflet for further information
Reckitt Benckiser
Licence Holder:
Reckitt Benckiser Healthcare (UK) Ltd. SL1 3UH.
PL 00063/0650
We welcome your comments and suggestions. Please write to:
Consumer Information, Freepost HU7831, Reckitt Benckiser Healthcare (UK) Limited, Hull. HU8 7BR
or call us free (UK only) on 0500 455 456
Wording prepared October 2010
Strepsils
Children 6+ Lozenges
RB003563
Ink & Varnish Free Area