

PLEASE NOTE:

This is a peel and reveal leaflet which was submitted with the Renewal application back in 2013, incorporating a label and a patient information leaflet

This artwork only applies to the Tetra pack - small, round tube containing 10 lozenges, which is not currently marketed.

Patient Information Leaflet

Strepsils Warm Lozenge

2,4-Dichlorobenzyl alcohol 1.2mg

Amylmetacresol 0.6mg

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take Strepsils Warm 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 talk to a doctor if your symptoms worsen or do not improve after 3 days.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Strepsils Warm Lozenges are and what they are used for
2. What you need to know before you take Strepsils Warm Lozenges
3. How to take Strepsils Warm Lozenges
4. Possible side effects
5. How to store Strepsils Warm Lozenges
6. Contents of the pack and other information

1. WHAT STREPSILS WARM LOZENGES ARE AND WHAT THEY ARE USED FOR

Strepsils Warm Lozenges contains two antiseptic ingredients for use in throat preparations and are used for the symptomatic relief of mouth and throat infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STREPSILS WARM LOZENGES

This product is recommended for adults, children (over 12 years old) and the elderly. Children under 12 years old should not use this product.

Do not take this product if you:

- Are allergic (hypersensitive to amylmetacresol, 2,4-dichlorobenzyl alcohol or any of the other ingredients shown in section 6
- If you are under 12 years old
- If you have rare hereditary problems with fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency

Warnings and precautions

Tell your doctor or pharmacy is you are taking or have recently taken any other medicines, including medicines obtained without a prescription

Pregnancy, breast-feeding and fertility

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 of Strepsils Warm

This product contains sucrose and glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. HOW TO TAKE STREPSILS WARM

For oral administration.

Adults, children over 12 years and elderly – 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 12 years.

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 Warm can cause side effects, although not everybody gets them. If you experience any hypersensitivity, abdominal pain, nausea, oral discomfort or develop a rash, 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.

Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2: Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE STREPSILS WARM

Keep out of the reach and sight of children. Do not use this product after the expiry date which is stated on the tube. The expiry date refers to the last day of that month and the year.

Do not store above 25°C. Keep the tube tightly closed in order to protect against moisture. Use within 3 months of opening. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measure will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Strepsils Warm Lozenges contain

This product contains the active ingredients amylmetacresol 0.6mg and 2,4-dichlorobenzyl alcohol 1.2mg. It also contains: fruity plum flavour, soothing cream flavour, warm sensation flavour, warm

ginger spice flavour, tartaric acid, anthocyanins (E163), medium chain triglycerides, propylene glycol (may cause skin irritation), sucrose and glucose. Each lozenge contains 1.1g of glucose and 1.4g of sucrose.

What Strepsils Warm Lozenges look like and contents of the pack

A red to purple lozenge with characteristic warm taste of plum and ginger, embossed on both sides with Strepsils brand icon.

Each pack contains 10 lozenges.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer: Reckitt Benckiser Healthcare International Limited, Nottingham, NG90 2DB, UK.

This leaflet was last revised in May 2017

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (TETRA TUBE)
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1. NAME OF THE MEDICINAL PRODUCT

Strepsils Warm Lozenge

2. STATEMENT OF ACTIVE SUBSTANCE(S)

2,4-Dichlorobenzyl alcohol 1.2mg

Amylmetacresol 0.6mg

Soothing effective relief for sore throats

3. LIST OF EXCIPIENTS

Active ingredients: 2,4-dichlorobenzyl alcohol and amylmetacresol. Also contains propylene glycol, glucose and sucrose, see peel and read leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

10 lozenges

5. METHOD AND ROUTE(S) OF ADMINISTRATION

How to use: Adults, children over 12 years and elderly: 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 12 years.

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

Keep out of the sight and reach of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep the tube tightly closed in order to protect from moisture. Do not use after the expiry date shown on the pack.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

PA Holder: Reckitt Benckiser Ireland Ltd., 7 Riverwalk, Citywest Business Campus, Dublin 24

Manufacturer: Reckitt Benckiser Healthcare (UK) Ltd., Hull, HU8 7DS, UK.

Product queries: Telephone: 01-630429

12. MARKETING AUTHORISATION NUMBER(S)

PA 979/58/1

13 BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Supply through general sales

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Strepsils Warm

