105mm

148mm

12mm

SCHEDULING STATUS

S0

PROPRIETARY NAME AND DOSAGE FORM
STREPSILS® COOLMINT (LOZENGE)
COMPOSITION
Each lozenge contains:
2,4 Dichlorobenzyl Alcohol 1,2 mg ; Amylmetacresol 0, 6 mg ; Sugar 2,5 g
PHARMACOLOGICAL CLASSIFICATION
A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.
PHARMACOLOGICAL ACTION
Pharmacodynamic Properties
Strepsils lozenges have disinfectant and antiseptic properties.
INDICATIONS
Indicated for the relief of minor mouth and throat infections including sore throat.
CONTRA-INDICATIONS
Hypersensitivity to any of the ingredients.
Children under the age of 12 years
WARNINGS
Contains sugar. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take this medicine.
INTERACTIONS
No clinically significant interactions are known.
PREGNANCY AND LACTATION
Safety has not been established.
DOSAGE AND DIRECTIONS FOR USE
Adults: One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours.
Children over 12 years: One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 8 lozenges in 24 hours.
SIDE-EFFECTS AND SPECIAL PRECAUTIONS
Side-Effects: The adverse reactions are ranked under headings of frequency, most frequent reactions first, using the following convention: Very common (> 1/10); common (> 1/100, ≤ 1/10); uncommon (>1/1 000, ≤1/100);
rare (> 1/10 000, ≤ 1/1000); very rare (≤ 1/ 10 000).
Very rare (≤ 1/ 10 000) : Hypersensitivity reactions.
Special Precautions: If symptoms persist for more than two days, consult your doctor.
Effects on ability to drive and use machines: No adverse effects are known.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.
IDENTIFICATION
A white to pale yellow coloured lozenge with a characteristic taste of mint and menthol and an "S" on both sides.
PRESENTATION
Blister Pack: 2, 4, 6, 8, 12, 16 or 24 lozenges
A clear 250 µm polyvinyl chloride (PVC) coated with 40 gsm of polyvynylidene chloride (PVdC) heat sealed to 20 µm aluminium foil blister pack.
Sachet: 2's
Cello-poly aluminium foil laminate consisting of 0.021 mm cellophane, 0.018 mm polyethylene, 0.030 mm aluminium and 0.025 mm polyethylene.
Tube: 10's
A white, opaque, injection-moulded, polypropylene container with a polyethylene push-fit cap with tamper evident band and desiccant (silica gel) beads enclosed by paper disc cover.
STORAGE INSTRUCTIONS
Store below 25 °C. KEEP OUT OF REACH OF CHILDREN.
REGISTRATION NUMBER
34/16.4/0502
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION CERTIFICATE
© 2007 Reckitt Benckiser Pharmaceuticals (Pty) Ltd.
8 Jet Park Road Elandsfontein 1601
DATE OF PUBLICATION OF THIS PACKAGE INSERT February 2003 Namibia: 13/16.4/0169 NS0

12mm

Pharmacode Reads This Way
First Bar
Last Bar

35mm

40mm

35mm

Pharmacode Reads This Way
First Bar
Last Bar

40mm

12mm

SKEDULERINGSTATUS

S0

EIENDOMSNAAM EN DOSEERVORM
STREPSILS® COOLMINT (SUIGTABLETTE)
SAMESTELLING
Elke suigtablet bevat
2,4 Dichloorbensiel-alkohol 1,2 mg ; Amielmetakresol 0,6 mg ; Suiker 2,5 g
FARMAKOLOGIESE KLASSIFIKASIE
A 16.4 Neus-antiseptikum en mond- en keelantiseptikum.
FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Strepsils suigtablette met antiseptiese en ontsmettende eienskappe.
INDIKASIES
Geïndikeer vir die verligting van mond- en keel-infeksies, insluitend seer keel.
KONTRA-INDIKASIES
Hipersensitiwiteit vir enige van die bestanddele. Kinders jonger as 12 jaar.
WAARSKUWINGS
Bevat suiker. Pasiënte met seldsame oorerflike probleme van fruktose-intoleransie, glukose-galaktose wanabsorpsie of gebrekkige sukrose-isomaltose behoort nie hierdie medisyne te neem nie.
INTERAKSIES
Geen klinies betekenisvolle interaksies is bekend nie.
SWANGERSKAP EN LAKTASIE
Veiligheid is nie bevestig nie.
DOSERING EN GEBRUIKSAANWYSINGS
Volwassenes: Los een suigtablet stadig in die mond elke 2 tot 3 ure tot 'n maksimum van 12 suigtablette binne 24 uur.
Kinders ouer as 12 jaar: Los een suigtablet stadig in die mond elke 2 tot 3 ure tot 'n maksimum van 8 suigtablette binne 24 uur.
NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS
Newe-effekte: Die nadelige reaksies word geklassifiseer onder opskrifte van veelvuldigheid, die mees herhalende reaksies eerste, met behulp van die volgende konvensie: Baie algemeen (>1/10); algemeen (>1/100, ≤ 1/10); ongewoon (> 1/1000 , ≤ 1/100), seldsaam (>1/10 000, ≤ 1/1000); baie seldsaam (≤ 1/ 10 000).
Baie seldsaam (≤ 1/ 10 000) : Hipersensitiwiteitsreaksies
Spesiale Voorsorgmaatreëls: Indien 'n seerkeel meer as twee dae lank duur, raadpleeg u geneesheer.
Uitwerking op bestuurvermoë en gebruik van masjinerie: Geen nadelige uitwerking bekend.
BEKENDE SIMPTOME VAN OORDOSERING EN BEHANDELING DAARVAN
Oordosering behoort geen probleme te veroorsaak nie, buiten maagderm-ongerief.
Behandeling behoort simptomaties te wees.
IDENTIFIKASIE
'n Wit tot liggeel-kleurige suigtablet met 'n kenmerkende smaak van ment en mentol en 'n "S" aan beide kante.
AANBIEDING
Stulpverpakking: 2, 4, 6, 8, 12, 16, of 24 suigtablette
'n Deursigtige 250 µm poliviniel-chloried (PVC) bedek met 40 gsm polivinilidien- chloried (PVdC) hitte-verseël tot 20 µm aluminiumfoelie borrelverpakking.
Sakkie: 2's
Sello-poli aluminiumfoelie gelamineerde verpakking bestaande uit 0.021 mm sellofaan, 0.018 mm poli-etileen, 0.030 mm aluminium en 0.025 mm poli-etileen.
Buisie: 10's
'n Wit, ondeursigtige, inspuiting-gevormde polipropileen houer met 'n poli-etileen stoot-pas dop met peuter-aanduidende en droogmakende (silika-jel) korrels, bedek deur papierskyf.
BERGINGSAANWYSINGS
Bewaar benede 25 °C. HOU BUITE BEREIK VAN KINDERS
REGISTRASIENOMMER
34/16.4/0502
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
© 2007 Reckitt Benckiser Pharmaceuticals (Edms) Bpk.
Jetparkweg 8 Elandsfontein 1601
DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET Februarie 2003

3002452

CUSTOMER INFO:
Please note, text has been adjusted to fit at 6pt.
Afrikaans side is laid out slightly different due to having extra text.

RB Artwork and Print Specification

Trident Reference No:	RB140271
ZEN Ref:	TR756574
Action:	B
Brand:	Strepsils
Category:	Throatcare
Segment Group:	Cool
Segment:	16
Pack Size:	16Pack
Market/Country:	South Africa
Date:	23/04/14

RBH Contact:	Tania Goncalves

Artwork Type: Commercial

Component Code (2D if applicable):	3002452
Parent Technical Packaging Specification:	D0070127
Finished Goods Code:	N/A
Supply Point:	RB Nottingham
Pharmacode No/NE:	1111010010(2001)
Edgemark Position:	N/A

CAD Cam Ref:	S-Lft-FB-148x105mm
Printer:	Chesapeake Tewkesbury
Substrate:	Paper White

Technical & Non Printing Items
Cutter
Cutter 2 (if applicable)
Guides
Guides 2 (if applicable)

Colours (Leaflet)
Process Black 1 LTH

BARCODE INFO

Barcode Type:	N/A
Barcode Number:	N/A
Magnification:	N/A
Truncated By:	N/A
Full Height:	N/A
Bar Height (Smallest Bar):	N/A
BWR:	N/A
Encoded Data:	N/A

Reckitt Benckiser

Reckitt Benckiser Healthcare (UK) Ltd,
Dansom Lane, Hull, HU8 7DS, U.K.

TRIDENT
Connaught House, Connaught Road,
Kingswood Business Park, Hull, HU7 3AP, England.
T: +44 (0) 1482 828100

Please note that any low resolution paper Canon colour copies associated with this job should be referred to for content, layout and colour separation only.

STUDIO USE ONLY Samantha Reilly v2.0
Sm•Art check results: G=0; O=1; R=0; - SR - 23/04/14 12:43:13

ARTWORK APPROVAL

Approved by Sonoco Trident on behalf of Reckitt Benckiser
Signed: _
Date: _

NOT APPROVED FOR COLOUR

UNDER NO CIRCUMSTANCES SHOULD THIS ARTWORK BE ALTERED WITHOUT PRIOR PERMISSION FROM TRIDENT.

mm 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 250 260 270 280 290

Production line			
Manufacturing site			
Pack Tech approver	1st	2nd	
Date			
Check Criteria	Details & Comments	Checks 1st	2nd
Approvals			
Market Approval			
Regulatory Approval			
3rd Party Approval			
Technical Drawing/Cutter ref no.			
PPI component code correct on artwork?			
Correct drawing for the production line?			
Profile shape & dimensions			
Graphics layout/orientation			
Unwind diagram (PPTD1022/1-20)			
Printable areas/bleed			
Varnish free areas			
Variable coding position & dimensions			
Varnish and print requirements			
Pre-printed headers (alignment and suitability)			
Embossing, Braille & Foil Blocking			
Separations on artwork			
Alignment within cutter			
Braille structure			
Verification Code Type; Pharma Code / 2D / OCV			
Bar sequence and/or number correct Position			
Size (height, width, spacing, font)			
Direction of read			
Light margins and print free areas			
Colour			
Repeat distance (reeled material)			
Bar code Type; EAN, ITF, Code39, etc			
Magnification / width and height			
Colour (e.g. black print on white background)			
Light margins & indicators			
Bearer bars & H gauges (if required)			
Symbol grade (Pass = A,B,C; Action = D,F)			
Bar code number (human readable)			
Bar code number (encoded & hidden data)			
Confirm bar code number from source			
Cross check related docs (JDE/PID)			
Photo-electric cell mark / edge marks			
Present & per Tech drawing?			
Correct pitch?			
Additional markings			
e-mark, recycle logo etc			
Legend box (RB specification)			
Correct component code			
Correct D spec			
Correct printer			
Correct Substrate			
A/W is set up appropriately for this substrate			
Edge mark details			
Pharmacode details			
Colours & print process			
Varnish			
Barcode information			
General details are correct			
Pass / Fail comments and Signature			
By approving the artwork referenced within this form I authorise it for release to the print supplier			
Additional Comments			

Version 001 14/2/2011

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ZEN Ref: TR756574
Action: B
Brand: Strepsils
Category: Throatcare
Segment Group: Cool
Segment: 16
Pack Size: 16Pack
Market/Country: South Africa
Date: 23/04/14

RBH Contact: Tania Goncalves

Artwork Type: Commercial

Component Code (2D if applicable): 3002452
Parent Technical Packaging Specification: D0070127
Finished Goods Code: N/A
Supply Point: RB Nottingham
Pharmacode No/NE: 1111010010(2001)
Edgemark Position: N/A

CAD Cam Ref: S-Lft-FB-148x105mm
Printer: Chesapeake Tewkesbury
Substrate: Paper White

Technical & Non Printing Items

- Cutter
- Cutter 2 (if applicable)
- Guides
- Guides 2 (if applicable)

Colours (Leaflet)

Process Black
1
LTH

BARCODE INFO

Barcode Type: N/A
Barcode Number: N/A
Magnification: N/A
Truncated By: N/A
Full Height: N/A
Bar Height (Smallest Bar): N/A
BWR: N/A
Encoded Data: N/A

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