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Strefen Eucalyptus and Manuka Honey Flavour 8.75mg Lozenges

Contains Flurbiprofen

INFORMATION FOR THE USER

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

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- **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.**
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. WHAT STREFEN EUCALYPTUS AND MANUKA HONEY FLAVOUR 8.75MG LOZENGES IS AND WHAT IT IS USED FOR

This medicine contains flurbiprofen. Flurbiprofen is a non-steroidal anti-inflammatory drug (NSAID) which has analgesic, antipyretic and anti-inflammatory properties. Flurbiprofen 8.75 mg lozenges are used for the short-term relief of symptoms of sore throat such as throat pain, soreness and swelling, and difficulty in swallowing in adults and adolescents over the age of 12 years.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE STREFEN EUCALYPTUS AND MANUKA HONEY FLAVOUR 8.75MG LOZENGES

Do not take these lozenges if you:

are allergic (hypersensitive) to Flurbiprofen or to any of the other ingredients of this medicine (listed in section 6); have ever had asthma, unexpected wheezing or shortness of breath, a runny nose, facial swelling or itchy rash (hives) after taking acetylsalicylic acid (aspirin) or any other NSAID medicine; currently have or have ever had two or more episodes of a stomach ulcer, intestinal ulcers, or gastrointestinal bleeding; have had gastrointestinal bleeding or perforation, severe colitis (inflammation of the bowel) or bleeding disorders when taking NSAID medicines in the past; are in the last 3 months of pregnancy; have severe heart, severe kidney or severe liver failure

Warnings and precautions

Talk to your doctor or pharmacist before taking Strefen Eucalyptus and Manuka Honey Flavour 8.75mg Lozenges if you:

have ever had asthma or suffer from allergies; have tonsillitis (inflamed tonsils) or think you may have a bacterial throat infection (as you may need antibiotics); have heart, kidney or liver problems; have had a stroke; have a history of bowel disease (ulcerative colitis, Crohn's disease); suffer from chronic autoimmune disease such as systemic lupus erythematosus and mixed connective tissue disease; are elderly, as you are more likely to experience the side effects listed in this leaflet; are in the first 6 months of pregnancy or breastfeeding; If you have high blood pressure; If you have analgesic-induced headache

Whilst using this medicine

At the first sign of any skin reaction (rash, peeling, blistering) or other sign of an allergic reaction, stop using the lozenge and consult a doctor at once. Report any unusual abdominal symptoms (especially bleeding) to your doctor. If you do not get better, you get worse, or develop new symptoms, talk to a doctor. The use of medicines containing flurbiprofen may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment (3 days).

Children

This medicine should not be used by children under the age of 12 years.

Other medicines and Strefen Eucalyptus and Manuka Honey Flavour 8.75mg Lozenges

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine. In particular, tell them if you are taking:

low dose acetylsalicylic acid (aspirin) (up to 75 mg daily); medicines for high blood pressure or heart failure (antihypertensives, cardiac glycosides); water tablets (diuretics, including potassium sparing drugs); medicines for thinning the blood (anticoagulants, antiplatelet agents); medicines for gout (probenecid, sulfinpyrazone); other NSAIDs including cyclooxygenase-2 selective inhibitors or corticosteroids (such as celecoxib, ibuprofen, diclofenac sodium or prednisolone); mifepristone (a medicine used for pregnancy termination); quinolone antibiotics (such as ciprofloxacin); cyclosporine or tacrolimus (to suppress the immune system); phenytoin (to treat epilepsy); methotrexate (to treat autoimmune diseases or cancer); lithium or SSRIs (for depression); oral antidiabetics (to treat diabetes); zidovudine (to treat HIV)

Taking this medicine with food, drink and alcohol.

Alcohol should be avoided during treatment with this medicine as it increases the risk of bleeding in the stomach or intestines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this medicine if you are **in the last 3 months of pregnancy.** If you are in the first 6 months of pregnancy or are breast-feeding, speak to your doctor before taking these lozenges. Flurbiprofen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that the lozenges, used occasionally, will affect your chances of becoming pregnant; however, tell your doctor before taking this medicine if you have problems becoming pregnant.

Driving and using machines

No studies on the effects on the ability to drive and use of machines have been performed. However, dizziness and visual disturbances are possible side effects after taking NSAIDs. If affected, do not drive or operate machinery.

This medicine contains Isomalt (E953), Liquid Maltitol (E965) and flavouring with Anise Alcohol, Benzyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Cinnamal, Cinnamyl Alcohol, Citral, Geraniol, Limonene and Linalool.

Strefen Eucalyptus and Manuka Honey Flavour 8.75mg Lozenges contains Isomalt (E953) 2032.18 mg/lozenge and Liquid Maltitol (E965) 509.03 mg/lozenge.

May have a mild laxative effect.

Calorific value 2.3 kcal/g maltitol or isomalt.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Anise Alcohol, Benzyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Cinnamal, Cinnamyl Alcohol, Citral, Geraniol, Limonene and Linalool may cause allergic reactions.

This medicine contains 0.00169 mg benzyl alcohol in each lozenge. Ask your doctor or pharmacist for advice if you have a liver or kidney disease or if you are pregnant or breast-feeding (see section 2. Pregnancy, breast-feeding and fertility). This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Benzyl alcohol may cause mild local irritation.

3. HOW TO USE STREFEN EUCALYPTUS AND MANUKA HONEY FLAVOUR 8.75MG LOZENGES

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults, the elderly and children aged 12 years and older:

Take one lozenge by mouth and suck slowly. Always move the lozenge around whilst sucking. The lozenges should start to work within 30 minutes. Then take one lozenge every 3-6 hours, if needed.

Do not take more than 5 lozenges in a 24 hour period.

Do not give to children under 12 years.

These lozenges are for short-term use only. You should take as few lozenges as you need for the shortest time necessary to relieve your symptoms. If mouth irritation occurs, flurbiprofen treatment should be withdrawn.

Do not take this medicine for more than 3 days unless your doctor tells you to. If you do not get better, you get worse, or if you develop new symptoms, talk to a doctor or pharmacist.

If you take more lozenges than you should

Talk to a doctor or pharmacist or go to your nearest hospital straight away. Symptoms of overdose include: feeling sick or being sick, stomach ache or, more rarely, diarrhoea. Ringing in the ears, headache and gastrointestinal bleeding is also possible.

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

If you forget to take this medicine

Do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines this medicine can cause side effects, although not everybody gets them.

STOP TAKING the medicine and seek immediate medical help if you develop:

signs of an allergic reaction such as asthma, unexplained wheezing or shortness of breath, itchiness, runny nose, skin rashes, etc.; swelling of the face, tongue or throat causing difficulty in breathing, racing heart and drop in blood pressure leading to shock (these can happen even on the first use of the medicine.); severe skin reactions such as peeling, blistering or flaking skin.

Tell your doctor or pharmacist if you notice any of the following effects or any effects not listed:

Common *(may affect up to 1 in 10 people)*

- dizziness, headache
- throat irritation
- mouth ulcers or pain in the mouth
- throat pain
- discomfort or unusual sensation in the mouth (such as warmth, burning, tingling, prickling, etc.)
- nausea and diarrhoea
- prickling and itching sensation in skin

Uncommon *(may affect up to 1 in 100 people)*

drowsiness; blistering in the mouth or throat, numbness in the throat; stomach bloating, abdominal pain, wind, constipation, indigestion, vomiting; dry mouth; burning sensation in the mouth, altered sense of taste; skin rashes, itchy skin; fever, pain; feeling sleepy or difficulty in falling asleep; worsening of asthma, wheezing, shortness of breath; reduced sensation in the throat

Rare *(may affect up to 1 in 1000 people)*

anaphylactic reaction

Frequency not known (cannot be estimated from the available data) anaemia, thrombocytopenia (low platelet count in the blood that can give rise to bruising and bleeding); swelling (oedema), high blood pressure, heart failure or attack; severe forms of skin reactions such as bullous reactions, including Stevens-Johnson syndrome and Lyell's syndrome and toxic epidermal necrolysis; hepatitis (inflammation of the liver)

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 also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE STREFEN EUCALYPTUS AND MANUKA HONEY FLAVOUR 8.75MG LOZENGES

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date stated on the pack and blister pack after EXP. The expiry date refers to the last day of that month
- Store below 25°C.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What this medicine contains:

The active ingredient (the ingredient which makes the medicine work) is flurbiprofen 8.75 mg. The other ingredients are: macrogol 300, potassium hydroxide (E525), ammonia caramel (E150c), curcumin (E100) (contains propylene glycol (E1520) and polysorbate 80), Honey and Eucalyptus flavour (contains Flavouring preparations, natural flavouring substances, Flavouring substances, Triacetin (E1518), Propylene Glycol (E1520), Anise Alcohol, Benzyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Cinnamal, Cinnamyl Alcohol, Citral, Geraniol, Limonene and Linalool), acesulfame potassium (E950), maltitol liquid (E965) and isomalt (E953).

What Strefen Eucalyptus and Manuka Honey Flavour 8.75mg Lozenges looks like and contents of the pack

The lozenges are circular in shape with an embossed brand logo and a pale brown to yellow colour, in opaque, white PVC/PVdC/Aluminium blisters and packed into cardboard cartons. The pack contains 8 or 16 lozenges. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Reckitt Benckiser Healthcare (UK) Limited, 103-105 Bath Road, Slough, SL1 3UH, United Kingdom

Manufacturer

RB NL Brands B.V., Schiphol Boulevard 207, 1118 BH Schiphol, Netherland

Produce licence number: PL 00063/0767

Date of revision: November 2023

P

50053487

Top Back

Pharmacode Reads This Way

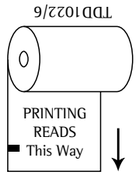
First Bar

Last Bar

83.6mm to centre of mark

72.5mm from first bar to bottom of leaflet

TDD1022/6



CUSTOMER INFO

Minimum Point Size =9.00pt

RB Artwork and Print Specification

Trident Reference No:	RB594135
ZEN Ref:	**TR3074402**
BrandWork Ref:	**RBL2310500**
Action:	**E**
Brand:	Strefen
Category:	Throatcare
Segment Group:	Eucalyptus and Manuka Honey
Segment:	16
Pack Size:	16 Pack
Market/Country:	UK
Date:	21/06/2024
RBH Contact:	Mannie Kwan

Artwork Type: BW Commercial

Component Code (2D if applicable):	**50053487**
2nd Component Code (if applicable):	**N/A**
Parent Technical Packaging Specification:	D0160125
Finished Goods Code:	**3290150**
Supply Point:	RB Nottingham
3rd Party Code:	N/A
Pharmacode No/NE:	10111110001 (3568)
Edgemark Position:	N/A
CAD Cam Ref:	S-LFT-D0160125-RF-209.55x148mm
Printer:	Medica Packaging Limited (Crewe, UK)
Substrate:	Paper White

Technical & Non Printing Items

Dieline; Dieline 2 (if applicable); Guides; Guides 2 (if applicable)

Colours

Black 1 1M

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TRIDENT

Connaught House, Connaught Road,
Kingswood Business Park, Hull, HU7 3AP, England.
T:+44 (0) 01482 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.

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

STUDIO USE ONLY Subramanian MarudhuPandiyan **v2.0**

BARCODE INFO

Barcode Type:	Pharmacode Standard
Code Value:	3568
Magnification:	100 %
Overall Height:	10 mm
Bar Height:	10 mm
BWR Applied:	0 Micrometre

mm 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220

Production line(s)				
Manufacturing site				
Pack Tech approver	1st	2nd		
Date				
Check Criteria	Details & Comments		Checks	
Approvals			1st	2nd
3rd Party Approval		☐ N/A	☐ Pass	☐ Pass
Technical Drawing/Cutter ref no./Legend box				
Component item code correct on artwork		☐ N/A	☐ Pass	☐ Pass
Correct D-spec and drawing for the production line		☐ N/A	☐ Pass	☐ Pass
Profile shape & dimensions		☐ N/A	☐ Pass	☐ Pass
Graphics layout/orientation		☐ N/A	☐ Pass	☐ Pass
Unwind diagram (PPTD1022/1-20)		☐ N/A	☐ Pass	☐ Pass
Printable areas/bleed		☐ N/A	☐ Pass	☐ Pass
Varnish free areas		☐ N/A	☐ Pass	☐ Pass
Variable coding position & dimensions				
Varnish and print requirements		☐ N/A	☐ Pass	☐ Pass
Pre-printed headers (alignment and suitability)		☐ N/A	☐ Pass	☐ Pass
Embossing and foil blocking		☐ N/A	☐ Pass	☐ Pass
Separations on artwork (Braille/Varnish/etc.)		☐ N/A	☐ Pass	☐ Pass
Alignment within cutter		☐ N/A	☐ Pass	☐ Pass
Braille structure (position/start cell/end cell)		☐ N/A	☐ Pass	☐ Pass
Verification Code Type: Pharma Code / 2D / OLV				
Bar sequence and/or number correct and in correct position		☐ N/A	☐ Pass	☐ Pass
2D barcode decode contains correct item code		☐ N/A	☐ Pass	☐ Pass
Size (height, width, spacing, font)		☐ N/A	☐ Pass	☐ Pass
Direction of read		☐ N/A	☐ Pass	☐ Pass
Light margins and print free areas		☐ N/A	☐ Pass	☐ Pass
Colour		☐ N/A	☐ Pass	☐ Pass
Repeat distance (reeled material)		☐ N/A	☐ Pass	☐ Pass
Cross check related docs ie CPBOM		☐ N/A	☐ Pass	☐ Pass
Bar code Type; EAN, ITF, Code39, etc				
Magnification / width and height		☐ N/A	☐ Pass	☐ Pass
Colour (e.g. black print on white background)		☐ N/A	☐ Pass	☐ Pass
Light margins & indicators		☐ N/A	☐ Pass	☐ Pass
Bearer bars & H gauges (if required)		☐ N/A	☐ Pass	☐ Pass
Bar code number (human readable)		☐ N/A	☐ Pass	☐ Pass
Bar code number (encoded & hidden data)		☐ N/A	☐ Pass	☐ Pass
Confirm bar code number from source		☐ N/A	☐ Pass	☐ Pass
Photo-electric cell mark / edge marks				
Present & per Tech drawing		☐ N/A	☐ Pass	☐ Pass
Correct pitch		☐ N/A	☐ Pass	☐ Pass
Additional markings				
e-mark, recycle logo etc		☐ N/A	☐ Pass	☐ Pass
Additional information				
Correct printer		☐ N/A	☐ Pass	☐ Pass
Correct Substrate		☐ N/A	☐ Pass	☐ Pass
Edge mark details		☐ N/A	☐ Pass	☐ Pass
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Varnish		☐ N/A	☐ Pass	☐ Pass
General details are correct		☐ N/A	☐ Pass	☐ Pass
Pass / Fail comments and Signature			☐ Pass	☐ Fail
By approving the artwork referenced within this form I authorise it for release to the print supplier				
Additional Comments				

Version 005 20/09/2022

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