ESSENTIAL INFORMATION FOR STREFEN HONEY & LEMON

Name and actives:
Strefen Honey & Lemon contains Flurbiprofen 8.75mg per lozenge

Indication:
Strefen Honey and Lemon are indicated for the short term symptomatic relief of sore throat in adults and children over the age of 12 years.

Dosage and administration:
Adults the elderly and children over the age of 12 years:
One lozenge sucked/dissolved slowly in the mouth every 3 - 6 hours as required. Maximum 5 lozenges in a 24 hour period.

It is recommended that this product should be used for a maximum of three days

Children: Not indicated for children under 12 years.

Elderly: A general dose recommendation cannot be given, since to date clinical experience is limited. The elderly are at increased risk of the serious consequences of adverse reactions.

Impaired hepatic: In patients with mild to moderate impairment of hepatic function no dose reduction is required. In patients with severe hepatic insufficiency flurbiprofen is contraindicated.

Impaired renal: In patients with mild to moderate impairment of renal function no dose reduction is required. In patients with severe renal insufficiency flurbiprofen is contraindicated.

For oromucosal administration and short-term use only.

As with all lozenges, to avoid local irritation, Strefen Honey and Lemon should be moved around the mouth whilst sucking. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms

Contraindications:
Hypersensitivity to flurbiprofen or any of the excipients in the product.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, bronchospasm, rhinitis, angioedema, or urticaria) in response to acetylsalicylic acid or other NSAIDs.

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration) and intestinal ulceration.

History of gastrointestinal bleeding or perforation, severe colitis, haemorrhagic or haematopoietic disorders related to previous NSAID therapy.

Last trimester of pregnancy. Severe heart failure, severe renal failure or severe hepatic failure.

Special warnings and precautions for use:
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms

Elderly population
The elderly have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal.

***Respiratory*:**
Bronchospasm may be precipitated in patients suffering from, or with a previous history of bronchial asthma or allergic disease. Flurbiprofen lozenges should be used with caution in these patients.

***Other NSAIDs*:**
The use of flurbiprofen lozenges with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section 4.5).

Systemic lupus erythematosus and mixed connective tissue disease:
Patients with systemic lupus erythematosus and mixed connective tissue disease may have an increased risk of aseptic meningitis (see section 4.8), however this effect is not usually seen with short term limited use products such as flurbiprofen lozenges.

Cardiovascular, Renal and Hepatic Impairment:
NSAIDs have been reported to cause nephrotoxicity in various forms including interstitial nephritis, nephrotic syndrome and renal failure. The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly, however, this effect is not usually seen with short term, limited use products such as flurbiprofen lozenges.

Cardiovascular and cerebrovascular effects:
Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.
Clinical trial and epidemiological data suggest that the use of NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for flurbiprofen when given at a daily dose of no more than 5 lozenges.

Hepatic:
Mild to moderate hepatic dysfunction (see sections 4.3 and 4.8)

Nervous System effects
Analgesic induced headache - In the event of prolonged use of analgesics or use beyond the regulations headache may occur, which must not be treated with increased doses of the medicinal product.

Gastrointestinal*:*
NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4.8)

Gastrointestinal bleeding, ulceration or perforation, which can be fatal has been reported with all NSAIDs at anytime during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see Section 4.3), and in the elderly, however this effect is not usually seen with short term limited use products such as flurbiprofen lozenges.
Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding) to their healthcare professional. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as acetylsalicylic acid (see section 4.5).
If GI bleeding or ulceration occurs in patients receiving flurbiprofen, the treatment should be withdrawn.

Dermatological:
Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDSs (see section 4.8). Flurbiprofen lozenges should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Infections:
Since in isolated cases an exacerbation of infective inflammations (e.g. development of necrotising fasciitis) has been described in temporal association with the use of systemic NSAIDs as a class, the patient is advised to consult a physician immediately if signs of a bacterial infection occur or worsen during the flurbiprofen lozenges therapy. It should be considered whether initiation of an anti-infective antibiotic therapy is indicated.

Sugar intolerance:
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

If the symptoms get worse or if new symptoms occur, the treatment should be re-evaluated.

If mouth irritation occurs, treatment should be withdrawn.
.
Undesirable effects:
Hypersensitivity reactions to NSAIDs have been reported and these may consist of:
(a) non-specific allergic reactions and anaphylaxis

(b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea

(c) various skin reactions e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme)

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that use of some NSAIDs, (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke), (see section 4.4). There is insufficient data to exclude such a risk for flurbiprofen 8.75 mg lozenges

The following list of adverse effects relates to those experienced with flurbiprofen at OTC doses for short-term use.

(Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1000 to <1/100), Rare (≥1/10000 to <1/1000), Very rare (<1/10000), not known (cannot be estimated from the available data))

Blood and lymphatic system disorders:
Not known: anaemia, thrombocytopenia.

Immune System disorders:
Rare: anaphylactic reaction

Psychiatric disorders:
Uncommon: insomnia

Cardiovascular and cerebrovascular disorders
Not known: Oedema, hypertension and cardiac failure

Nervous System disorders:
Common: dizziness, headache, parasthesia
Uncommon: somnolence

Respiratory, thoracic and mediastinal disorders:
Common: throat irritation
Uncommon: exacerbation of asthma and bronchospasm, dyspnoea, wheezing, oropharyngeal blistering, pharyngeal hypoaesthesia.

Gastrointestinal disorders:
Common: diarrhoea, mouth ulceration, nausea, oral pain, paraesthesia oral, oropharyngeal pain, oral discomfort (warm or burning feeling or tingling of the mouth).
Uncommon: abdominal distension, abdominal pain, constipation, dry mouth, dyspepsia, flatulence, glossodynia, dysgeusia, oral dysaesthesia, vomiting

Hepatobiliary disorders:
Not known: hepatitis

Skin and subcutaneous tissue disorders:
Uncommon: various skin rashes, pruritus.
Not known: severe forms of skin reaction such as bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

General disorders and administration site conditions:
Uncommon: pyrexia, pain

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

MRRP: £5.29 16 lozenges

Product licence number: PL 00063/0714
Product Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom
Legal category: P

Date of preparation: 04/08/2016

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Reckitt Benckiser Healthcare (UK) Ltd on: 0333 200 5345