ESSENTIAL INFORMATION STREFEN HONEY & LEMON™

Contains Flurbiprofen 8.75 mg per lozenge **Indication:** Symptomatic relief of sore throat **Dosage and administration: Adults 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. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 3 days. It is recommended that this product should be used for a maximum of three days. **Children:** Not indicated for children under 12 years. **Elderly:** No dose modification is required. As with all lozenges, to avoid local irritation, Strefen Honey and Lemon should be moved around the mouth whilst sucking. **Contraindications:** Hypersensitivity to flurbiprofen or any of the excipients in the product. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs. Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). History of gastrointestinal bleeding or perforation, related to previous NSAIDS therapy. Severe heart failure, renal failure or hepatic failure. Last trimester of pregnancy. **Special warnings and precautions for use: Pregnancy and lactation:** Whilst no teratogenic effects have been demonstrated in animal experiments, the use of Strefen Honey and Lemon should, if possible, be avoided during the first 6 months of pregnancy. During the 3rd trimester, flurbiprofen is contraindicated as there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. Flurbiprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely. **Undesirable effects:** Strefen Honey and Lemon have the potential for inducing transient local irritation of the buccal mucosa. The most frequently reported adverse event in clinical trials was taste perversion. Hypersensitivity reactions 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) The list of the following adverse effects relates to those experienced with NSAIDS at doses available over the counter for short-term use. In the treatment of chronic conditions, under longterm treatment, additional adverse effects may occur. **Hypersensitivity reactions:** Uncommon: Hypersensitivity reactions with urticaria and pruritis Very rare: severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, (anaphylaxis, angioedema or severe shock). Exacerbation of asthma and bronchospasm. **Gastrointestinal:** The most commonly observed adverse events are gastrointestinal in nature. Uncommon: abdominal pain, nausea, dyspepsia Rare: Diarrhoea, flatulence, constipation and vomiting Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis, sometimes fatal, particularly in the elderly. Ulcerative stomatitis, gastritis. Exacerbation of colitis and Crohn's disease. **Nervous System:** Uncommon: Headache, Very rare: Aseptic meningitis – single cases have been reported very rarely. **Renal:** Very rare: Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum and oedema. **Hepatic:** Very rare: liver disorders. **Haematological:** Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising. **Dermatological:** Uncommon: Various skin rashes Very rare: Severe forms of skin reactions such as bullous reactions including Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur. **Immune System:** In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed. Cardiovascular and Cerebrovascular Oedema, hypertension and cardiac failure, have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that the use of NSAIDS (particularly at high doses 2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke) **MRRP:** £3.99 for 16s lozenges **Drug Tariff Price:** £2.58 **Product licence number:** 00327/0135 **Product Licence Holder:** Crookes Healthcare Ltd., Nottingham NG2 3AA **Legal category:** P **Date of preparation:** 08/06/2012. For full information refer to SPC (http://www.medicines.org.uk/emc/).

All 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 0500 455 456