REFERENCES
1. Strefen. Summary of product characteristics. March 2021. Accessed July 2023. **2.** Data on file. Reckitt B (UK) Ltd. **3.** Limb M *et al. Int J Clin Pract.* 2009; 63:606–612. **4.** Blagden M *et al. Int J Clin Pract.* 2002; 58:95–100. **5.** Shephard A *et al.* Abstract presented at the European Congress of Clinical Microbiology and Infectious Diseases, 27–30 April 2013, Berlin, Germany.

ESSENTIAL INFORMATION:
Strefen Honey and Lemon
Active Ingredient (s): Flurbiprofen 8.75mg
Indications: 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 & Administration:** Posology 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 (see section 4.3). 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 (see section 4.3). **Method of administration:** 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 (see section 4.4) **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. (See section 4.6) Severe heart failure, severe renal failure or severe hepatic failure (see section 4.4)
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.

Important Information about some of the ingredients of this medicine

- This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One lozenge contains no more than 21.38 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.
- This medicine contains 1.407 g Sucrose per lozenge and 1.069 g Glucose per lozenge. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase isomaltase insufficiency should not take this medicine.
- This medicine contains sulphites, which may rarely cause severe hypersensitivity reactions and bronchospasm.
- This medicine contains fragrance with Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool. Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool may cause allergic reactions.
- This medicine contains Butylated hydroxyanisole (E320) (present in Lemon flavour) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Fertility, Pregnancy and Lactation:
Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, flurbiprofen should not be given unless clearly necessary. If flurbiprofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose
• the fœtus to:
  o cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension).
  o renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;
• the mother and the neonate, at the end of pregnancy, to:
  o possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
  o inhibition of uterine contractions resulting in delayed or prolonged labour.
Consequently, flurbiprofen is contraindicated during the third trimester of pregnancy.
Lactation: In limited studies, flurbiprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely. However, because of possible adverse effects of NSAIDs on breast-fed infants, Strefen Honey & Lemon lozenges are not recommended for use in nursing mothers.
Fertility: There is some evidence that drugs which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.
Side 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 or search for MHRA Yellow Card in the Google Play or Apple App Store.
Legal Classification: P
Licence Holder: Reckitt Benckiser Healthcare (UK) Ltd, 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom. **Licence Number:** PL 00063/0714. **Price** (ex VAT): £5.29. **Last Revised:** 15/03/2021.