Summary of Product Characteristics

STREPSILS INTENSIVE HONEY LEMON LOZENGES

1. NAME OF THE MEDICINAL PRODUCT

Strepsils Intensive Honey Lemon Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Flurbiprofen 8.75mg

3. PHARMACEUTICAL FORM

Strepsils Intensive Honey Lemon Lozenges is round, intagliated, pale yellow to brown, high-boiled lozenge with a characteristic taste of Honey and Lemon.

4. Clinical particulars

4.1 Therapeutic indications

For the symptomatic relief of mouth and throat infections

4.2 Posology and method of administration

Posology

Treatment should be administered for the shortest duration necessary to control symptoms, up to a maximum of 3 days.

Adults: One lozenge every 3-6 hours as required. Do not exceed 5 lozenges in any 24-hour period

Children over the age of 12 years: As above for adults.

Children under 12 years: 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

Method of administration

For oromucosal administration. To be dissolved slowly in the mouth.

As with all lozenges, to avoid local irritation, flurbiprofen lozenges should be moved around the mouth whilst sucking. If mouth irritation occurs, treatment should be withdrawn.

4.3 Contraindications

Hypersensitivity to flurbiprofen or to any of the excipients listed in the product. The product is also contraindicated in the following categories of patients:

1. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, bronchospasm or urticaria) in response to ibuprofen, acetylsalicylic acid (Aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs).
2. Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
3. History of gastrointestinal bleeding or perforation, severe colitis, haemorrhagic or haematopoietic disorders related to previous NSAID therapy.
4. Severe heart failure, severe hepatic failure or severe renal failure (see section 4.4).
5. Last trimester of pregnancy.
6. Use in children under 12 years of age.

4.4. Special Warnings and precaution for Use

- This medication must be used with caution in the elderly because of increased frequency of adverse events to NSAIDs.
- Flurbiprofen should be used with caution in patients suffering from or with a previous history of bronchial asthma or allergic disease
- The use of flurbiprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided
- Patients with systemic lupus erythematosus and mixed connective tissue disease may have an increased risk of aseptic meningitis, though not usually seen in short term and limited use
- This drug must be used with caution in patients with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly
- Caution is required 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.
- Analgesic-induced headache may occur with prolonged use, which must not be treated with increased doses of the medicinal product.
- It must be given with care in patients with gastrointestinal disease as NSAIDs may exacerbate this condition. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation
- The use of NSAIDs on very rare instances can lead to Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis.

- Since in isolated cases an exacerbation of infective inflammations (e.g. development of necrotizing 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 therapy.

4.5 **Interaction with other medicinal products and other forms of interaction**

Flurbiprofen should be avoided in combination with Acetylsalicylic Acid and other NSAIDs

Flurbiprofen should be used with caution in combination with drugs such as Anticoagulants, Anti-platelet agents and Selective Serotonin Reuptake Inhibitors (SSRIs), Antihypertensives (ACE inhibitors and Angiotensin II Antagonists) and Diuretics, Alcohol, Cardiac Glycosides, Ciclosporin, Corticosteroids, Methotrexate, Lithium, Mifepristone, Quinolone Antibiotics, Tacrolimus and Zidovudine

4.6 **Fertility, pregnancy and lactation**

Pregnancy

Flurbiprofen should be avoided during the first and second trimesters of pregnancy. During the third trimester, the use of flurbiprofen is contraindicated.

Breast-feeding

In limited studies, flurbiprofen appears in the breast milk in a very low concentration and is unlikely to affect the breast-fed infant adversely. Flurbiprofen can be used during breast-feeding.

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.

4.7 **Effects on ability to drive and use machines**

The product has no or negligible influence on the ability to drive and use machines

4.8. **Undesirable Effects**

The list of the following adverse effects relates to those experienced with flurbiprofen at OTC doses, in short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Not known	Anaemia, thrombocytopenia
Immune System Disorders	Rare	Anaphylactic reaction
	Not known	Hypersensitivity[1]

Psychiatric Disorders	Uncommon	Insomnia
Nervous System Disorders	Common	Dizziness, headache, paraesthesia
	Uncommon	Somnolence
Cardiac disorders	Not known	Cardiac failure, oedema
Vascular disorders	Not known	Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Common	Throat irritation
	Uncommon	Exacerbation of asthma and bronchospasm, dyspnoea, oropharyngeal blistering, pharyngeal hypoaesthesia
Gastrointestinal Disorders	Common	Diarrhoea, mouth ulceration, nausea, oral pain, paraesthesia oral, oropharyngeal pain, oral discomfort[2]
	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	Pruritus
	Not known	Severe forms of skin reaction such as bullous reactions, including Stevens-Johnson Syndrome, erythema multiform and toxic epidermal necrolysis
General Disorders and Administration Site Conditions	Uncommon	Pyrexia, pain

4.9 **Overdose**

Symptoms:

Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache, and gastrointestinal bleeding are also possible. In more serious poisoning with NSAIDs, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation, blurred vision and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning with NSAIDs metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management:

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal and if necessary, correction of serum electrolytes if the patient presents within one hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions

should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma. There is no specific antidote to flurbiprofen.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Respiratory System; Throat preparations. Flurbiprofen is a non-steroidal anti-inflammatory drug which has potent analgesic, anti-inflammatory and anti-pyretic activity. The drug's therapeutic effects as a non-steroidal anti-inflammatory drug are thought to result from inhibitory activity on prostaglandin synthesis. According to studies using the whole-body assay, flurbiprofen is a mixed COX-1/COX-2 inhibitor with some selectivity towards COX-1.

Pre-clinical studies suggest that the R (-) enantiomer of flurbiprofen and related NSAIDs may relieve pain by acting on the central nervous system.

Reduction in throat soreness was observed after 15 minutes while onset of pain relief and reduction of throat swelling was observed 30 minutes after taking a lozenge. Duration of action extended up to 3 hours.

5.2 Pharmacokinetics properties

Flurbiprofen lozenges is rapidly absorbed from the formulation with peak plasma concentrations reached after 30-40 minutes. Peak concentrations are achieved more rapidly than an equivalent swallowed dose but are of similar magnitude.

Flurbiprofen is rapidly distributed throughout the body. It is mainly metabolised by hydroxylation and conjugation in the liver. Excretion occurs via the kidneys.

Flurbiprofen is extensively bound to plasma proteins and has an elimination half-life of 3 to 6 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300, Potassium Hydroxide, Lemon Flavour, Levomenthol, Liquid Glucose, Liquid Glucose, Liquid Sucrose, Honey

6.2 Shelf life

2 years

6.3 Special precautions for storage

Do not store above 25°C

6.4. Nature and contents of container

A blister push-through pack consisting of hard temper aluminium foil heat-sealed to a PVC/PVDC blister. The tray contains 8 lozenges to give a pack size of 16 lozenges in a cardboard carton.

6.5 **Special precautions for disposal and other handling**

None

7 **APPLICANT/MANUFACTURER**

Applicant: Reckitt Benckiser Nigeria Limited

Manufacturer: Reckitt Benckiser Healthcare International (UK) Limited, Nottingham Site Thane Road, Nottinghamshire NG90 2DB United Kingdom

This leaflet was revised: July 2022.

The leaflet gives you the most important information. If you have any questions after you have read it, ask your doctor or pharmacist who will be able to help.

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