Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stresils Intensive Sugar Free Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient flurbiprofen BP 8.75 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Lozenge

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Strepsils Intensive Sugar Free Lozenges are indicated for the symptomatic relief of sore throat.

4.2 Posology and method of 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. 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, Strepsils Intensive Sugar Free Orange Lozenges should be moved around the mouth whilst sucking.

4.3 Contraindications

Hypersensitivity to flurbiprofen, aspirin, other non-steroidal anti-inflammatory drug (NSAIDs) or other lozenge ingredients. Existing or history of peptic ulceration. History of bronchospasm, rhinitis, or urticaria associated with aspirin or other NSAIDs.

4.4 Special warnings and precautions for use

Bronchospasm may be precipitated in patients suffering from, or with a previous history of bronchial asthma. Strepsils Intensive Sugar Free Lozenges should be used with caution in these patients.
NSAID’s have been reported to cause nephrotoxicity in various forms including interstitial nephritis, nephrotic syndrome and renal failure. In patients with renal, cardiac or hepatic impairment, caution is required since the use of the NSAID’s may result in the deterioration of renal function. Caution is required in patients with hypertension.

Flurbiprofen can prolong bleeding time and caution is required in patients with a potential for abnormal bleeding.

Undesirable effects may be minimised by using the minimum effective dose for the shortest possible duration.

Strepsils Intensive Sugar Free Lozenges should not be taken with other NSAID's.

4.5 Interaction with other medicinal products and other forms of interaction

Studies have shown that the diuretic response to frusemide can occasionally be reduced by Flurbiprofen. Similarly, interference with the action of anticoagulants has occasionally been reported. Other studies have failed to show any interaction between Flurbiprofen and digoxin, tolbutamide or antacids. NSAIDs may diminish the effect of antihypertensive drugs.

4.6 Pregnancy and lactation

The use of Strepsils Intensive Sugar Free Lozenges during pregnancy should be avoided. Regular use of NSAID's during the third trimester of pregnancy may result in the premature closure of the foetal ductus arteriosus in utero and persistent pulmonary hypertension of the newborn. Flurbiprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Dyspepsia, nausea, vomiting, gastrointestinal haemorrhage, diarrhoea, mouth ulcers, fluid retention, oedema and abdominal pain have been reported. Exacerbation of peptic ulceration and perforation have also been reported.

Urticaria, angioedema and rashes of varying descriptions have been reported.

Very rarely, jaundice and thrombocytopenia, have been reported. These are usually reversible on withdrawal of the drug.

Very rarely, aplastic anaemia and agranulocytosis have been reported in association with the use of flurbiprofen but causality has not been established.

Strepsils Intensive Sugar Free Lozenges have the potential for inducing transient local irritation of the buccal mucosa. The most frequently reported adverse events in clinical trials was taste perversion.

Bronchospasm may be precipitated in patients with a history of aspirin sensitive asthma.

4.9 Overdose

Symptoms of overdose may include nausea, vomiting, headache, drowsiness, blurred vision, gastro-intestinal irritation and dizziness. Treatment should consist of gastric lavage and if necessary correction of serum electrolytes. There is no specific antidote to flurbiprofen.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Flurbiprofen is a non-steroidal anti-inflammatory drug which has potent analgesic, antipyretic and anti-inflammatory properties which are thought to result from the drug's ability to inhibit prostaglandins synthesis.

The onset of pain relief, reduction in throat soreness and reduction in throat swelling was observed 30 minutes after taking a lozenge and duration of action extended to 2-3 hours.

5.2 Pharmacokinetic properties

Flurbiprofen is rapidly absorbed following the use of Strepsils Intensive Sugar Free Orange Lozenges with plasma concentrations peaking at 30 - 40 minutes. Peak concentrations are achieved more rapidly than, but are of similar magnitude to, those achieved after an equivalent swallowed dose.

Flurbiprofen is rapidly distributed throughout the body. It is mainly metabolised by hydroxylation and excreted via the kidneys.

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

Flurbiprofen is excreted in very small amounts in human milk (less than 0.05 µg/ml).

5.3 Preclinical safety data

In rats exposed to 0.4 mg/kg/day and above during pregnancy an increased incidence of stillborn pregnancy has been observed. However, the relevance of this fact to humans is doubtful and not reflected in human experience with flurbiprofen so far.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Orange Flavour
Calcium Carbonate
Povidone
Colloidal Silicon Dioxide
Magnesium Stearate
Maltitol, Liquid
Isomalt
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Store below 25°C in a dry place.

6.5 Nature and contents of container

A push through strip consisting of 250 microns opaque PVC/PVdC (polyvinyl chloride/polyvinyl di-chloride) blister, heat sealed to hard tempered 20 micron aluminium foil. Each blister contains 8 lozenges and there are two blister strips in each pack.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 43/25/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT