

STREPSILS INTENSIVE PACKAGE INSERT

SCHEDULING STATUS

Schedule 1

PROPRIETARY NAME (AND DOSAGE FORM)

STREPSILS INTENSIVE Lozenges

COMPOSITION

Each lozenge contains 8,75 mg flurbiprofen.

PHARMACOLOGICAL CLASSIFICATION

A 16. Ear, nose and throat preparations.

PHARMACOLOGICAL ACTION

Pharmacodynamics

Flurbiprofen is non-steroidal anti-inflammatory drug which has analgesic, antipyretic and anti-inflammatory properties. Flurbiprofen is an inhibitor of prostaglandin synthetase enzymes.

Pharmacokinetics

Flurbiprofen is rapidly absorbed following the use of STREPSILS INTENSIVE 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 microlitres per ml).

INDICATIONS

STREPSILS INTENSIVE is indicated for the relief of pain or sore throats. For bacterial sore throat, appropriate antibiotics should be prescribed.

CONTRA-INDICATIONS

Hypersensitivity to flurbiprofen, aspirin or other NSAIDs. Existing or history of peptic ulceration. History of bronchospasm, rhinitis or urticaria associated with aspirin or other NSAIDs.

Pregnancy and lactation.

Children under the age of 12 years.

WARNINGS

Use of NSAIDs during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus in utero and persistent pulmonary hypertension of the newborn. Flurbiprofen appears in the breast milk.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years:

One lozenge sucked/dissolved slowly in the mouth every 3-6 hours as required. Maximum of 5 lozenges in a 24 hour period. It is recommended that this product should not be used for more than 3 days. If symptoms persist, talk to your doctor.

Children:

Not indicated for children under 12 years.

Elderly:

No dose modification is required.

To avoid local irritation, STREPSILS INTENSIVE lozenges should be moved around the mouth whilst sucking.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Side-effects:

Changes in taste sensation and paraesthesia in the mouth are a common side effect.

Dyspepsia, nausea, vomiting, gastrointestinal haemorrhage, diarrhoea, mouth ulcers, fluid retention and oedema may occur.

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

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

Very rarely aplastic anaemia and agranulocytosis have been reported in association with the use of flurbiprofen.

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

Special precautions

Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Asthmatics and patients allergic to any other pain relievers should only take STREPSILS INTENSIVE on the advice of a doctor.

NSAIDs 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 NSAIDs 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 (such as patients on anticoagulant therapy). Caution is advised in patients with bleeding disorders.

STREPSILS INTENSIVE should not be taken with other NSAIDs.

INTERACTIONS

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

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Keep to the stated dose.

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

IDENTIFICATION

A round, pale yellow to brown lozenge with a characteristic honey and lemon taste and the S-brand icon intagliated on both sides.

PRESENTATION

Cartons containing 12 blister packed lozenges.

STORAGE INSTRUCTIONS

Store below 25 °C in a dry place, protected from light.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

35/16/0015

NAME AND BUSINESS ADDRESS OF THE HODER OF THE CERTIFICATE OF REGISTRATION

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

Elandsfontein

1601

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