SCHEDULING STATUS S0

PROPRIETARY NAME (AND DOSAGE FORM)

FLUFIGHT (Solution)

COMPOSITION Each 5 ml contains:
Sodium Salicylate 187,5 mg
Preserved with Methyl Hydroxybenzoate 0,2% m/v
Contains alcohol 4,8% v/v
Contains Tartrazine

PHARMACOLOGICAL CLASSIFICATION A 2.7 Anti-pyretics or anti-pyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION It has analgesic, anti-inflammatory and antipyretic properties.

INDICATIONS FluFight is indicated in the treatment of headache, fever, colds and influenza, painful menstrual periods, toothache, and muscle and joint pain.

CONTRA-INDICATIONS Hypersensitivity to any of the ingredients. Hypersensitivity to aspirin, other salicylates, non-steroidal anti-inflammatory agents or tartrazine dye. Contra-indicated in patients prone to dyspepsia, those with peptic ulcers, haemorrhagic disorders such as haemophilia, thrombocytopenia or platelet function disorders, gout, asthma and patients receiving oral anticoagulant therapy.
Not to be taken during the first three months or last three months of pregnancy unless prescribed by a doctor.

WARNINGS Salicylates have been implicated in Reye's syndrome, a rare but serious illness in children and teenagers with chickenpox or influenza. A doctor should be consulted before the product is used in such patients.
Consult a doctor if pain or fever persists or gets worse, if new symptoms occur or if redness and swelling is present, as these could be signs of a serious condition. Do not use this product continuously for more than 10 days for pain or for more than 3 days for fever, without consulting a doctor.
Regular use of non-steroidal anti-inflammatory drugs during the third trimester of pregnancy may result in premature closure of the foetal ductus arteriosus in utero and possibly in persistent pulmonary hypertension of the newborn. The onset of labour may be delayed and its duration increased. To be used with caution in patients with liver or renal disease and only under the supervision of a doctor. Toxic effects are more likely in the elderly and those suffering from dehydration, due to reduced renal function. If ringing in the ears or loss of hearing occurs, consult a doctor before taking any more of this product. Do not take this product if you are presently taking a prescription medicine for anticoagulation, diabetes, gout or arthritis unless directed by a doctor. Do not take this product if you have high blood pressure, or are on a sodium restricted diet except on the advice and under the supervision of a doctor. The product should be discontinued several days before scheduled surgical procedures.
This product contains FD&C Yellow No.5 (Tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of Tartrazine sensitivity in the general population is currently thought to be low, it is frequently seen in patients who also have aspirin sensitivity.

DOSAGE AND DIRECTIONS FOR USE

Adults: 10 - 15 ml every four hours as required while symptoms persist.

Children and teenagers: Should not be given without consulting your doctor because of the risk of Reye's syndrome (see Warnings).

SIDE EFFECTS AND SPECIAL PRECAUTIONS

The commonest side effect is gastrointestinal disturbance such as nausea, dyspepsia and vomiting. Irritation of the gastric mucosa with erosion, ulceration, haematemesis and melaena may occur. Gastrointestinal bleeding may lead to iron deficiency anaemia on long term therapy. Salicylates may cause hepatotoxicity, particularly in patients with juvenile idiopathic arthritis, or other connective tissue disorders. Salicylates may increase the bleeding time and may cause hypoprothrombinaemia. It may cause other blood disorders including thrombocytopenia. Side effects may include rhinitis, urticaria and other skin eruptions, angioneurotic oedema and worsening of asthma.

Interactions: Salicylates potentiate the effects of anticoagulants. Prolonged concurrent use of paracetamol with salicylates increases the risk of adverse renal effects. Concurrent use of non-steroidal anti-inflammatory drugs increases the risk of gastrointestinal side effects. Concurrent use of corticosteroids increases the risk of gastrointestinal side effects. The excretion of salicylates may be increased by corticosteroids so that a higher dose is required to achieve a therapeutic effect. This may lead to signs of salicylate toxicity on withdrawal of corticosteroids. Urinary alkalinisers increase salicylate excretion so reducing the effectiveness of salicylates. Antidiabetic agents including insulin may be potentiated by salicylates. Salicylates interfere with the uricosuric action of probenecid. There is an increased risk of haemorrhage with other agents that inhibit platelet aggregation (penicillins, valproic acid, dipyridamole), thrombolytic agents and heparin. Salicylates displace methotrexate from its binding sites and reduce its renal clearance leading to toxic plasma levels.

Interference with laboratory tests: Salicylates may produce falsely increased results for blood creatinine, urate (low dose aspirin), and urea. Falsely decreased results may be obtained for blood thyroxine and urate (>4 g/ day aspirin) and for urinary 5-HIAA (with nitrosonaphthol method). Urinary VMA (HMMA) levels may be falsely increased or decreased depending on the method of analysis. Urinary glucose oxidase: Aspirin may cause a false negative test in the presence of glycosuria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT Mild chronic salicylate intoxication occurs after repeated administration of large doses. Symptoms include dizziness, tinnitus, deafness, sweating, nausea and vomiting, headache and confusion, and may be controlled by reducing the dosage. Symptoms of acute overdosage include hyperventilation, fever, restlessness, ketosis, respiratory alkalosis and metabolic acidosis. Depression of the central nervous system may lead to coma, and cardiovascular and respiratory failure may occur. In children drowsiness and metabolic acidosis commonly occur. Hypoglycaemia may be severe. In acute salicylate overdosage the stomach should be emptied, and activated charcoal administered. Fluid and electrolyte management is the mainstay of treatment with the immediate aim being correction of acidosis, hyperpyrexia, hypokalaemia and dehydration.

IDENTIFICATION A brown liquid with the characteristic smell of chloroform and menthol.

PRESENTATION In amber PVC bottles of 100 ml and amber HDPE containers of 2,5 l.

STORAGE INSTRUCTIONS Store at or below 25°C.
KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER C779 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF APPLICANT

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