

Panodin[®] SR

Etodolac USP

COMPOSITION

Panodin[®] SR: Each film-coated tablet contains Etodolac USP 600 mg in a sustained release formulation.

PHARMACOLOGY

Etodolac is a non-steroidal anti-inflammatory drug (NSAID). It inhibits the formation of prostaglandins. The inhibition of prostaglandin synthesis observed with Etodolac differs from that of other NSAIDs. Studies in human cell models have confirmed that Etodolac is selective for the inhibition of COX-2. Experiments have shown Etodolac to have marked anti-inflammatory activity, being more potent than several clinically established NSAIDs.

Etodolac is well absorbed following oral administration. Etodolac is highly bound to serum proteins. The elimination half-life averages seven hours. The primary route of excretion is in the urine, mostly in the form of metabolites.

INDICATION

Panodin[®] SR (Etodolac) is indicated for acute or long-term use in rheumatoid arthritis and osteoarthritis.

DOSAGE AND ADMINISTRATION

Adults: One tablet daily, swallowed whole with water.

Children: For the treatment of Juvenile Idiopathic Arthritis: One tablet daily in those weighing 31 to 45 kg.

Safety and effectiveness in pediatric patients below the age of 6 years have not been established.

CONTRAINDICATION AND PRECAUTION

Etodolac should not be used in patients who are hypersensitive to it.

Etodolac should not be used in patients with severe heart failure. It should not be used in patients with active peptic ulceration or a history of peptic ulcer disease (including gastrointestinal haemorrhage due to another non-steroidal anti-inflammatory drug). Etodolac should not be administered to patients who experience asthma, rhinitis or urticaria during therapy with aspirin or other non-steroidal anti-inflammatory drugs.

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

SIDE EFFECT

Reported side effects include nausea, epigastric pain, diarrhoea, indigestion, heartburn, flatulence, abdominal pain, constipation, vomiting, ulcerative stomatitis, dyspepsia, gastritis, haematemesis, melaena, rectal bleeding, colitis, vasculitis, headaches, dizziness, abnormal vision, pyrexia, drowsiness, tinnitus, rash, pruritus, fatigue, depression, insomnia, confusion, paraesthesia, tremor, weakness/malaise, dyspnoea, palpitations, bilirubinuria, hepatic function abnormalities and jaundice, urinary frequency, dysuria, angioedema, anaphylactoid reaction, photosensitivity and urticaria.

More serious adverse reactions which may occasionally occur are gastrointestinal ulceration and peptic ulceration.

Occasionally blood disorders have been reported including thrombocytopenia, neutropenia, agranulocytosis and anaemia.

DRUG INTERACTION

Since Etodolac is extensively protein-bound, it may be necessary to modify the dosage of other highly protein-bound drugs.

The concomitant administration of Warfarin and Etodolac should not require a dosage adjustment of either drug, however it has rarely led to prolonged prothrombin times, therefore caution should be exercised when Etodolac is administered with Warfarin.

Concomitant use of Ciclosporin, Methotrexate, Digoxin, or Lithium with NSAIDs may cause an increase in serum levels of these compounds and associated toxicities.

Care should also be taken in patients treated with any of the following drugs as interactions have been reported in some patients: Anti-hypertensives, Mifepristone, other Analgesics, Corticosteroids and Quinolone Antibiotics.

USE IN PREGNANCY AND LACTATION

Safety in human pregnancy has not been established and Etodolac should not be used during pregnancy.

Safety of Etodolac use during lactation has not been established and as such its use in nursing mothers should be avoided.

STORAGE

Store at a cool and dry place protected from light & moisture. Keep out of reach of children.

HOW SUPPLIED

Panodin[®] SR: Box containing 3X10 tablets in blister pack.

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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Revision No. : 00