Edolac®

Etodolac

Description
Etodolac is a non-steroidal anti-inflammatory drug (NSAID). It inhibits the formation of prostaglandins.

Mode of action
Etodolac is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits antiinflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of etodolac, like that of other NSAIDs, is not completely understood, but may be related to prostaglandin synthetase inhibition.

Pharmacokinetics
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.

Composition
Edolac® 300 Capsule: Each capsule contains Etodolac USP 300 mg.
Edolac® 600 ER Tablet: Each extended release tablet contains Etodolac USP 600 mg.

Indications
Etodolac is indicated:
A. For acute and long-term use in the management of signs and symptoms of the following:
1. Osteoarthritis
2. Rheumatoid arthritis
B.For the management of acute pain

Dosage & administration
Adult and over 18 years:
Edolac® Capsule: 600 mg daily in 1-2 divided doses.
Edolac® 600 ER Tablet: Once daily.

Contraindications
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.

Use in pregnancy & 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.

Side effects
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.

Precautions
Etodolac cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered solely if a decision is made to discontinue corticosteroids. The pharmacological activity of etodolac in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

Drug interactions
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 asinteractions have been reported in some patients: Anti-hypertensives, Mifepristone, other Analgesics, Corticosteroids and Quinolone Antibiotics.

Over dosage
Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur and coma has occurred following massive ibuprofen or mefenamic-acid overdose. Hypertension, acute renal failure, and respiratory depression may occur but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following overdose. Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of the urine, hemodialysis, or hemoperfusion would probably not be useful due to Etodolac's high protein binding.

Storage
Store in a cool and dry place, protected from light.

Packaging
Edolac® 300 Capsule: Each carton contains 6X5 capsules in blister pack.
Edolac® 600 ER Tablet: Each carton contains 6X2 tablets in blister pack.

Opsonin
Opsonin Pharma
Ideas for healthcare

Manufactured by
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