Edolar

Edolar film-coated tablet 300 mg, 10 film-coated tablets
Edolar Fort film-coated tablet 400 mg, 10 film-coated tablets
Edolar film tablet 500 mg, 14 film tablets

COMPOSITION: Each tablet contains **300 mg, 400 mg and 500 mg** etodolac and auxiliary materials lactose and titanium dioxide.

PHARMACOLOGICAL PROPERTIES: Pharmacodynamics: Etodolac is a nonsteroidal anti-inflammatory drug (NSAID) that exhibits anti-inflammatory, analgesic, and antipyretic activities.

INDICATIONS: Etodolac is indicated for the management of signs and symptoms of the osteoarthritis, rheumatoid arthritis, ankylosing spondylitis and for the management of acute pain.

CONTRAINDICATIONS: Etodolac is contraindicated in patients with known hypersensitivity to Etodolac. Etodolac should not be given to patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients. Etodolac is contraindicated patients with active gastric and duodenal ulcer and should not be used third trimester of pregnancy.

WARNINGS AND PRECAUTIONS: Gastrointestinal effects: NSAIDs, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine or large intestine, which can be serious. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Minor upper GI problems such as dyspepsia can often observed during NSAIDs treatment. Therefore, physicians should inform patients about the signs and/or symptoms of serious GI toxicity such as bleeding and ulceration. Therefore, people who do not already have gastrointestinal complaints in the ulceration and bleeding must be careful, patient and serious gastrointestinal toxicity symptoms / findings should be given information about. Previously, any factors (age, gender, etc.) increasing the risk has not been reported except known risk factors such as a serious gastrointestinal event or alcoholism and smoking. But the patients which are elderly and have bad general situation tolerate ulceration and bleeding worse than other patients. Anaphylactoid reactions: As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to Etodolac. Etodolac, should not be given to patients with the aspirin triad (asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs). Advanced renal disease: Like the other NSAIDs, etodolac treatment should begin by carefully renal function monitored to the patients with advanced renal disease (creatinine clearence value of <30 ml / min.). Renal Effects: Long-term administration of NSAIDs has resulted with renal toxicity. Patients at greater risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state. Nervous system effects: İn overdose or high dose confusion, agitation and hallucination are usually seen. However, these effects can be seen in the lower dose in the elderly than the young people. Hepatic effects: Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including Etodolac. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continuing therapy. Increases of the transaminases returns by treatment discontinuation. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), Etodolac should be discontinued. Hematological effects: Anemia is sometimes seen in patients receiving NSAIDs including Etodolac. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including Etodolac should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

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Moreover, all drugs that inhibit prostaglandin biosynthesis may affect vascular **response the platelet function and** the amount of bleeding. Fluid retention and edema: Fluid retention and edema have been observed in some patients taking NSAIDs. Etodolac should be used with caution in patients with fluid retention, hypertension and cardiac decompansation. Pre-existing astma: Approximately %10 of patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthmas has been associated with severe bronchospasm which can be fatal. Since cross reactivity, including bronchospasm, between aspirin and other nonsteroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, Etodolac capsules and tablets, USP should not be administered to patients with this form of aspirin sensitivity and should be used with caution in all patients with pre-existing asthma. Etodolac should be applied with caution to the patients which use anticoagulants and corticosteroid.

Pediatric use: Safety and effectiveness in pediatric patients have not been established. Geriatric use: As with any NSAID, must be careful in the treatment of elderly and adjusting the individual etodolac dose and must be careful when dose increasing. It has been identified that because of side effects of NSAIDs (especially gastrointestinal effects), elderly patients are less tolerated than young people. However, in patients with age 65 or over the side effects profile of etodolac did not differ from the general population.

USE IN PREGNANCY AND BREASTFEEDING PERIOD: Use in pregnancy: **pregnancy category is C.** There are no adequate and well-controlled studies in pregnant women. Etodolac should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.In late pregnancy, the third trimester, as with other NSAIDs, Etodolac should be avoided because it may cause premature closure of the ductus arteriosus. Use in breastfeeding mothers: It is not known whether etodalac is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Etodolac a decision should be made whether to discontinue nursing or to discontinue the drug taking into account the importance of the drug to the mother. Impact on the use of tools and machines: There is any information about the effects to the tool and machine use.

SIDE EFFECTS / ADVERSE EFFECTS: Etodolac is generally well tolerated. In patients taking Etodolac or other NSAIDs, the most frequently reported adverse experiences occurring in approximately ≥1% of patients are: All body - chills and fever. Gastrointestinal system - abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea, gastritis,vomiting. Nervous system - astenia / fatigue, dizziness, depression, nervousness. Skin and soft tissue - pruritus, rash. Special senses - blurred vision, tinnitus. Urogenital system - disuria, polyuria. Nöromusküler and skeletal system - weaknesses.

DRUG INTERACTIONS: Antacids: The concomitant administration of antacids has no apparent effect on the extent of absorption of Etodolac. However, antacids can decrease the peak concentration reached by 15% to 20% but have no detectable effect on the time-to-peak. Aspirin: When Etodolac is administered with aspirin, its protein binding is reduced, although the clearance of free Etodolac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of Etodolac and aspirin is not generally recommended because of the potential of increased adverse effects. Phenylbutazone: Phenylbutazone causes increase (by about 80%) in the free fraction of Etodolac. Although in vivo studies have not been done to see if Etodolac clearance is changed by coadministration of phenylbutazone, it is not recommended that they be coadministered.

DOSAGE AND ADMINSTRATION: As with other NSAIDs, after observing the response to initial therapy with Etodolac the dose and frequency should be adjusted to suit an individual patient's needs.

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Rheumatic diseases: The recommended dose of Etodolac for the management of the signs and symptoms of osteoarthritis or rheumatoid arthritis and ankylosing spondylitis is 600-1200 mg. Total administrated dose may be divided 2 or 3 in equal doses. In chronic conditions, a therapeutic response to therapy with Etodolac is sometimes seen within one week of therapy, but most often is observed by two weeks. After a satisfactory response has been achieved, the patient's dose should be reviewed and adjusted as required. Acute pain: The recommended total daily dose of Etodolac for acute pain is 1200 mg, given as 200-400 mg every 6 to 8 hours.

STORAGE CONDITIONS: Keep under 25°C at room temperature. (< 25°C). Should be kept out of the sight and reach of children and in its package.

AVAILABLE FORMS:

EDOLAR Film-coated tablets 300 mg, blister packs of 10 tablets

EDOLAR FORT Film-coated tablets 400 mg, blister packs of 10 tablets

EDOLAR Film tablets 500 mg, blister packs of 14 tablets.

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