SPMC
Diclofenac Sodium Delayed Release Tablets USP 50 mg

PRESENTATION:

Diclofenac Sodium Delayed Release tablets USP 50 mg packs of 500 tablets, packs of 1000 tablets and Blister 200's (20x10). Each Brown color, circular bi convex enteric coated tablets contain Diclofenac Sodium USP 50 mg.

INDICATIONS DOSAGE:

Pain and inflammation in rheumatoid disease (including juvenile arthritis) and other musculoskeletal disorders; acute gout; postoperative pain.

75-150mg daily in 2-3 divided doses.

CONTRA-INDICATIONS:

history of asthma. history of confirmed or suspected cerebrovascular bleeding history of hemorrhagic diathesis. hypovolaemia. operations with high risk of haemorrhage with systemic use Active gastro-intestinal bleeding. Active gastro-intestinal ulceration. avoid suppositories in proctitis. cerebrovascular disease. history of gastrointestinal bleeding related to previous NSAID therapy. history of gastro-intestinal perforation related to previous NSAID therapy. history of recurrent gastro-intestinal haemorrhage (two or more distinct episodes). history of recurrent gastro-intestinal ulceration (two or more distinct episodes). ischemic heart disease. mild to severe heart failure. peripheral arterial disease

SIDE EFFECTS:

SPECIFIC SIDE-EFFECTS

Common or very common

With systemic use Appetite decreased. diarrhoea. Dizziness gastrointestinal discomfort. gastrointestinal disorders. headache. nausea. oedema. Rash (discontinue). Skin reactions. vertigo. vomiting

Uncommon With systemic use

Chest pain. heart failure. myocardialinfarction. palpitations**Rare or very rare**With systemic use Acute kidney injury. agranulocytosis. alopecia. anaemia. angioedema. anxiety. Aplastic anaemia. asthma. confusion. constipation. Crohn's disease. depression. disorientation. drowsiness. dyspnoea. erectile dysfunction. haemolytic anaemia. hemorrhage. hearing impairment. hepatic disorders. hypersensitivity. hypertension. hypotension. irritability. leucopenia. memory loss. meningitis aseptic (patients with connective-tissue disorders such as systemic lupus erythematosus may be especially susceptible). Nephritis tubulointerstitial. nephrotic syndrome. oral disorders. pancreatitis. paranesthesia. photosensitivity reaction. pneumonitis. proteinuria. psychotic disorder. Renal papillary necrosis. seizure. sensation abnormal. Severe cutaneous adverse reactions (SCARs). shock. Sleep disorders. stroke. taste altered. thrombocytopenia. tremor. vasculitis. vision disorders

Frequency not known

With systemic use Fertility decreased female. fluid retention. hallucination. malaise. optic neuritis. Platelet aggregation inhibition with topical use Hair color changes

SIDE-EFFECTS, FURTHER INFORMATION

For information about cardiovascular and gastrointestinal side-effects, and a possible exacerbation of symptoms in asthma, see Nonsteroidal anti-inflammatory drugs with topical use Topical application of large amounts of diclofenac can result in systemic effects.

CAUTIONS:

With systemic use Allergic disorders. cardiac impairment (NSAIDs may impair renal function). coagulation defects. connective-tissue disorders. Crohn's disease (may be exacerbated). elderly (risk of serious side-effects and fatalities). history of cardiac failure. hypertension. Left ventricular dysfunction. oedema. risk factors for cardiovascular events. ulcerative colitis (may be exacerbated

PREGNANCY:

With systemic use Avoid unless the potential benefit outweighs the risk. Avoid during the third trimester (risk of closure of fetal ductus arteriosus in utero and possibly persistent pulmonary hypertension of the newborn); onset of labor may be delayed and duration may be increased. With topical use Patient packs for topical preparations carry a warning to avoid during pregnancy

CONCEPTION AND CONTRACEPTION

With systemic use Caution—long-term use of some NSAIDs is associated with reduced female fertility, which is reversible on stopping treatment.

HEPATIC IMPAIRMENT:

With systemic use with caution; there is an increased risk of gastro-intestinal bleeding and fluid retention. Avoid in severe liver disease.

RENAL IMPAIRMENT:

With systemic use Avoid if possible or use with caution. Avoid in severe impairment. With intravenous use Avoid intravenous use if serum creatinine greater than 160 micromole/liter. Contraindicated in moderate or severe renal impairment. Dose adjustments with systemic use the lowest effective dose should be used for the shortest possible duration. Monitoring With systemic use in renal impairment monitor renal function; sodium and water retention may occur and renal function may deteriorate, possibly leading to renal failure.

ALLERGY AND CROSS-SENSITIVITY

Contra-indicated in patients with a history of hypersensitivity to aspirin or any other NSAID—which includes those in whom attacks of asthma, angioedema, urticaria or rhinitis have been precipitated by aspirin or any other NSAID.

BREAST FEEDING:

With systemic use with caution during breast-feeding. Amount in milk too small to be harmful. With topical use Patient packs for topical preparations carry a warning to avoid during breast-feeding.

ADVICE TO PATIENTS:

As an enteric-coated tablet, it disintegrates and dissolves directly in the intestine, in which Diclofenac is absorbed rapidly. Therefore, gastric irritation is minimized. If dyspeptic symptoms such as heartburns, regurgitation, and abdominal discomfort occur stop the drug immediately & consult your physician. Patients undergoing prolonged treatment should be monitored as a precautionary measure (eg: renal, hepatic function and blood counts). Do not break or chew the tablets when administering.

INTERACTIONS:

Corticosteroids: increase the risk of gastro-intestinal bleeding & ulceration. Cardiac Glycosides: may exacerbate heart failure, reduce GFR, and increase plasma - cardiac glycoside concentration. Cytotoxic: excretion of methotrexate may be reduced. Lithium: excretion reduces. ACE inhibitors-increased the risk of renal impairment when NSAID given with ACE inhibitors, also hypotensive effect antagonized. Analgesics- avoid concomitant use of NSAIDs with NSAIDs or aspirin. Anticoagulant-Diclofenac increases the anticoagulant effect of coumarins. Beta blockers- NSAIDs antagonize hypotensive effect of beta-blockers. Clopidogrel-increased the risk of bleeding when given with clopidogrel. Diuretics- risk of nephrotoxicity of NSAIDs increased by diuretics.

STORAGE:

Keep tightly closed in cool and dry place. Protect from light. Store below 30^0C. do not crush or chew tablets. Keep away from children.

Manufactured by:
State Pharmaceutical Manufacturing Corporation
No.11, Sir John Kotalawala Mawatha,
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