

# DIX-TR

Diclofenac Sodium

## Composition

**DIX-TR Capsule** : Each capsule contains Diclofenac Sodium BP 100 mg as timed- release enteric coated pellets.

## Pharmacology

**DIX-TR** (Diclofenac Sodium) is a potent non-steroidal anti-inflammatory drug (NSAID) that exhibits analgesic, anti-inflammatory, and antipyretic properties. Its mode of action is based on the inhibition of prostaglandin synthesis. In **DIX-TR**, Diclofenac Sodium encapsulated as timed-release enteric coated pellets which ensure less GI complication, prolong pharmacological action and reduce dose frequency that improve patient compliance.

## Indication

**DIX-TR** (Diclofenac Sodium) is indicated for the relief of pain and inflammation in various conditions :

- Musculoskeletal and joint disorders : rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, degenerative joint diseases and juvenile arthritis.
- Peri-articular disorders : bursitis and tenditis
- Soft tissue disorders : sprain and strains
- Other painful condition : renal colic, acute gout, dysmenorrhea, migraine, dental pain and following some surgical procedures
- Also for the management of fever

## Dosage and Administration

One **DIX-TR** Capsule once daily, preferably after food.

## Contraindication

**DIX-TR** (Diclofenac Sodium) is contraindicated in i. Previous history of hypersensitivity to Diclofenac Sodium, or another NSAID ii. Who experience attack of asthma, bronchospasm, acute rhinitis, urticaria or edema after use of similar drugs (e.g. aspirin or other NSAIDs) iii. Active or suspected hemorrhage, active peptic ulcer, Crohn's disease or ulcerative colitis iv. With serious heart diseases v. the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. vi. porphyria

## Precaution

Diclofenac Sodium should be used with caution in i. bronchial asthma or other chronic diseases of the pulmonary tract as well as in persons prone to allergy ii. hepatic, renal or cardiac insufficiency and hypertension iii. considerable dehydration iv. fluid retention or heart failure v. coagulation disorders or patients receiving anticoagulants vi. elder patients.

## Side Effect

Most frequently reported : abdominal pain, diarrhea, dyspepsia, GI bleeding/ulceration, heartburn, nausea, headache, dizziness, edema, pruritus, rashes and tinnitus. Reported occasionally : congestive heart failure, hypertension, hepatitis, jaundice, blood disorders, depression, drowsiness, insomnia, nervousness, vertigo, bronchospasm, hematuria, photosensitivity, dysuria, oliguria, renal disturbance.

## Use in Pregnancy and Lactation

**Pregnancy** : Pregnancy category C. Because of the known effects of NSAIDs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy should be avoided.

**Lactation** : Diclofenac Sodium is excreted in breast-milk. Because of the potential for serious adverse reactions in nursing infants, decide whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## Drug Interaction

Anticoagulants : anticoagulant effect may enhanced. Antidepressants (SSRIs, Venlafaxine, Clopidogrel, Iloprost, Pentoxifylline, Sibutramine) : increased risk of bleeding. Antidiabetics (Sulfonylurea) : hypoglycemic effect may enhanced. Antiepileptic (Phenytoin) : possibly enhance effects of Phenytoin. Antihypertensive (Beta-blockers, Calcium-channel blockers, Clonidine, Diazoxide, Methyl dopa, Moxonidine, Nitrate, Hydralazine, Minoxidil, Nitroprusside) : NSAIDs antagonize their hypotensive effect. Diuretics : risk of nephrotoxicity of NSAIDs increased and also antagonism of diuretic effect. Cardiac Glycosides : plasma concentration of cardiac glycosides is increased. Corticosteroids : increased risk of GI bleeding and ulceration. Other NSAIDs and Aspirin : Concomitant use should be avoided. Cytotoxics (Methotrexate), Lithium, Baclofen : NSAIDs reduce their excretion, increased risk of toxicity. Aminoglycoside : plasma concentration of Aminoglycoside is increased. Antipsychotic (Haloperidol) : reports of severe drowsiness. Sucralfate, Colestyramine : Plasma concentration of Diclofenac Sodium is reduced.

## Storage

Store in cool dry place and away from light. Keep out of the reach of children.

## Packaging

**DIX-TR** Capsule : Box containing 10 x10's & 5 x 10's capsule in Alu-PVC strips