Composition : Diclofenac Sodium + Misoprostol; (50mg+0.2mg) & (75mg+0.2mg) Tablet.

Indications : It is indicated for treatment of the signs and symptoms of osteoarthritis or rheumatoid arthritis in patients at high risk of developing NSAID-induced gastric and duodenal ulcers and their complications.

Dosage and administration : Osteoarthritis: The recommended dosage for maximal GI mucosal protection is Nopain Extra 50 tid. For patients who experience intolerance, Nopain Extra 75 bid or Nopain Extra 50 bid can be used. Rheumatoid Arthritis: The recommended dosage is Nopain Extra 50 tid or qid. For patients who experience intolerance, Nopain Extra 75 bid or Nopain Extra 50 bid can be used. Special Dosing Considerations: Nopain Extra contains misoprostol, which provides protection against gastric and duodenal ulcers. For gastric ulcer prevention, the 0.2mg qid and tid regimens are therapeutically equivalent, but more protective than the bid regimen. Or, as directed by the registered physician.

Contraindications : This drug is contraindicated in patients with hypersensitivity to diclofenac or to misoprostol or other prostaglandins. This drug should not be given to patients who have experienced asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.

Use in pregnancy and lactation : In late pregnancy, as with other NSAIDs, this drug should be avoided because it may cause premature closure of the ductus arteriosus.

Side effects : This drug can cause more abdominal pain, diarrhea and other GI symptoms. Diarrhea and abdominal pain developed early in the course of therapy, and were usually selflimited (resolved after 2 to 7 days). Rare instances of profound diarrhea leading to severe dehydration have been reported in patients receiving misoprostol.

Precautions : This drug cannot be expected to substitute for corticosteroids or to treat

Nopain Extra Tablet

corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

Drug interactions : ACE Inhibitors: Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. Digoxin: Elevated digoxin levels have been reported in patients receiving digoxin and diclofenac sodium. Warfarin: Users of warfarin and NSAIDs drugs together have a risk of serious bleeding greater than users of either drug alone. Cyclosporine: This drug, like other NSAID containing products, may affect renal prostaglandins. Ingestion of this drug may increase cyclosporine nephrotoxicity. Antacids: Antacids reduce the bioavailability of misoprostol acid. Antacids may also delay absorption of diclofenac sodium. Diuretics: Clinical studies, have shown that this drug can reduce the natriuretic effect of furosemide and thiazides in some patients. **Packing:**

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Nopain Extra 50 : 2x10's tablets. Nopain Extra 75 : 3x10's tablets.