GROFENAC®

Composition: 1 tablet contains: diclofenac sodium 50 mg, excipients.

Properties: Grofenac contains a nonsteroidal active substance with anti-rheumatic, anti-inflammatory, analgesic and antipyretic activity. Inhibition of prostaglandin synthesis is thought to play an important role in its mode of action. Prostaglandins play a crucial role in inflammatory reactions, pain and fever. The tablets are covered with a gastroresistant coating.

Indications: Severe, acute pain due to inflammatory and degenerative joint diseases: rheumatoid arthritis, ankylosing spondylitis and osteoarthritis including vertebral arthritis, painful vertebral syndromes, extra-articular arthrosis, acute episodes of gout, painful inflammation and swelling following trauma or surgery, painful inflammatory conditions in gynecology such as primary dysmenorrhea, adnexitis.

Contra-indications: Peptic ulcer; known allergy to the active substance. In patients who have experienced asthma, urticaria or acute rhinitis after taking acetylsalicylic acid or other prostaglandin synthetase inhibitors.

Precautions: Patients with gastrointestinal disorders, a history of peptic ulcer, chronic ulcerative colitis, Crohn's disease or impaired liver function should be closely monitored. Treatment should be discontinued if abnormal liver function tests or other manifestations such as eosinophilia or skin eruption persist. Special caution should be exercised in patients with heart or renal failure, in the elderly, in patients on diuretic therapy and in hypovolemia of the extracellular space regardless of cause. Grofenac should not be used during the last trimester of pregnancy.

Adverse effects: Gastrointestinal: epigastric discomfort, other gastrointestinal symptoms. Rarely: peptic ulcer associated or not with perforation, gastrointestinal bleeding. Nervous system: headache, obnubilation, dizziness. Rarely: asthenia. Skin: cutaneous eruptions. Rarely: urticaria. Kidneys: isolated reports of acute renal failure, hematuria, proteinuria. Liver: elevation of serum transaminases. Rarely: hepatitis with or without jaundice. Hematologic: isolated reports of thrombocytopenia, leukopenia, agranulocytosis, hemolytic anemia, aplastic anemia. Allergic: rarely: asthma, systemic anaphylactic/anaphylactoid reactions, including hypotension. Other systems: rarely: oedema.

Interactions: Diclofenac can increase plasma levels of lithium and digoxin when given concurrently. Concomitant treatment with potassium sparing diuretics may cause hyperkalemia. Concomitant use of an anticoagulant may increase the risk of bleeding. Diclofenac can increase the hematologic toxicity of methotrexate. Systemic administration of several NSAIDs or glucocorticoids can increase the frequency of adverse reactions. Concomitant treatment with oral antidiabetics may cause hypo/hyperglycemic reactions.

Dosage: Grofenac 50 mg : The starting dosage is 100 mg to 150 mg daily. The dosage may then be tapered to the lowest effective dose for mild symptoms or long-term therapy. The dosage is generally fractionated into two or three doses taken with water at mealtimes. Grofenac 50 may be combined with other forms of Grofenac.
Pediatric dosage : Grofenac is contra-indicated in children under 12 years of age.

Presentations: box of 20 and 100 tablets.