CODAL-SYNTO

Controls pain and inflammation

Taks®

Diclofenac Sodium

Taks® 50mg enteric-coated tablets

Summary of SPC for Taks®

Name of the Medicinal Product:	Taks®.
Qualitative and Quantitative Composition:	Each tablet contains 50mg of diclofenac sodium.
Pharmaceutical Form:	Gastro-resistant tablets.
Therapeutic Indications:	Adults and Elderly: Relief of all grades of pain and inflammation in a wide range of conditions, including: Arthritic conditions, rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, acute gout; Acute musculo-skeletal disorders, tendinitis, tenosynovitis, bursitis; Other painful conditions as a result of trauma, including fracture, low back pain, sprains and strains, dislocations, orthopaedic, dental and other minor surgical procedures. Children: Not recommended.
Posology and Method of Administration:	Adults: 75mg - 150mg daily, in two or three divided doses. Maximum daily dose is 150mg. Elderly: The lowest effective dosage should be used in frail elderly patients or those with low body weight. Paediatric population: Not recommended.
Contraindications:	Hypersensitivity; Active, gastric or intestinal ulcer, bleeding or perforation; History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy; Active, or history of recurrent peptic ulcer/haemmorrhage; Severe hepatic, renal or cardiac failure; Last trimester of pregnancy; In patients whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other NSAIDs; Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.
Special Warnings and Precautions for Use:	Elderly, frail elderly patients or those with a low body weight; Taks® contains lactose, propylene glycol, sunset yellow and tartrazine. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Propylene glycol may cause alcohol-like symptoms. Sunset yellow and tartrazine may cause allergic reactions; Gastrointestinal bleeding; Hepatic effects; Renal effects; Haematological effects; Pre-existing asthma; Cardiovascular and cerebrovascular effects; Systemic lupus erythematosus (SLE) and mixed connective tissue disorders; Skin effects; Female fertility.
Interactions with other Medicaments and other forms of Interaction:	Lithium; Digoxin; Diuretics and antihypertensive agents; Drugs known to cause hyperkalemia; Anticoagulants and anti-platelet agents; Antidiabetic agents; Methotrexate; Ciclosporin; Tacrolimus; Quinolone antibacterials; Other NSAIDs including COX2 selective inhibitors and corticosteroids; SSRIs; Cardiac glycosides; Mifepristone; Phenytoin; Colestipol and cholestyramine; Potent CYP2C9 inhibitors.
Pregnancy and Lactation:	If diclofenac is used by a woman attempting to conceive, or during the 1st trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Diclofenac is contraindicated during the third trimester of pregnancy. Diclofenac should not be administered during breast feeding.
Undesirable effects:	Headache, dizziness; Vertigo; Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia; Transaminases increased; Rash.
Date of Revision of the Text:	08/2016.

MAH: Codal-Synto Ltd.