CHYMORAL-AP

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for CHYMORAL AP (Trypsin-Chymotrypsin with 50,000 Armour Units of Enzymatic Activity, Aceclofenac 100mg and Paracetamol 325mg tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Trypsin and Chymotrypsin are two types of proteases originally synthesized in the pancreas in the inactive form of zymogen precursors (trypsinogen and chymotrypsinogen) for the purpose of stopping unnecessary cellular activity and controlling when and where enzyme activity occurs. Aceclofenac and paracetamol are NSAIDs.

INDICATION: Acute or chronic osteoarthritis, rheumatoid arthritis and spondyloarthritis, spondylosis and other ortho-degenerative disorders, pain management; Surgery: Post-operative wounds, oedema and haematoma, prevention of inflammation of the stitching; Gynecology: pelvic inflammatory disease, caesarean section, episiotomy and hysterectomy; Dentistry: tooth extraction, peri apical abscess, maxillofacial surgery; Ophthalmology: ocular trauma such as macular edema, black eye, hyphema, uveal tract inflammation, subconjunctival hemorrhage; ENT: auricular septal hematoma, nasal fractures, parapharyngeal abscess; Orthopedics: Post-traumatic edema, soft tissue injury, fractures & dislocation, sports injury, sprains & strains, intervertebral disc herniation (sciatica or PID); Ophtalmology: ocular trauma such as macular oedema, black eye, hyphema, uveal tract inflammation, subconjunctival haemorrhage, extra-ocular trauma.

DOSAGE AND ADMINISTRATION: As directed by the Physician. The dose and dose frequency will be decided under the supervision of qualified physician.

CONTRAINDICATION: Hypersensitivity to aceclofenac, paracetamol, trypsin-chymotrypsin or to any of the excipients; Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding); previous hypersensitivity reactions (asthma, rhinitis, angioedema or urticaria) to NSAIDs; Severe heart failure, hepatic failure and renal failure; history of GI bleeding/performation; pregnancy (especially third trimester). As an adjunctive therapy in management of inflammatory edema due to injury, surgery, infection or dental procedures; high vitreous pressure.

WARNINGS & PRECAUTIONS: When used in the eye, it can cause increase in pressure in the eye and other eye conditions such as uveitis, paralysis of the iris, and keratitis; Not be employed in patients with severe hepatic insufficiency or renal damage or irregularities of blood clotting mechanism; To be used with caution during Lactation, or in the elderly, children, pregnancy and patients with irregularities of blood clotting mechanism; female attempting to conceive; serious dermatological reactions; SLE and mixed connective tissue disease; ulcerative colitis, crohn's disease; drugs increase the risk of bleeding or ulceration; gastrointestinal bleeding, ulceration and perforation; uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease; previous history of respiratory disorders.

DRUG INTERACTION: Trypsin/Chymotrypsin: Systemic proteases may increase the effectiveness of herbal supplements. Chymotrypsin is also known to interact with alcohol. Antibiotics: increase in the levels of the semi synthetic penicillin antibiotics and interact with chloramphenicol. Anticoagulants: CHYMORAL should not be administered concurrently with anti-coagulants. **Aceclofenac:** Antihypertensive agent's effect reduced; reduced diuretics effect; Diuretics, cyclosporine, tacrolimus increase nephrotoxic effect of NSAIDs; NSAIDs may exacerbate cardiac failure, reduce GFR (glomerular filtration rate) and increase plasma glycoside levels; decreased elimination of lithium and methotrexate, corticosteroids increase risk of gastrointestinal ulceration or bleeding; anti-coagulants effect enhanced; risk of convulsion with quinolone antibiotics; SSRIs enhance risk of bleeding; increased risk of haematological toxicity with zidovudine; isolated reports of hypoglycaemic and hyperglycaemic effects with anti-diabetics. **Paracetamol:** Cholestyramine: paracetamol absorption reduced; metoclopramide and domperidone: absorption increased; Chloramphenicol: Increased plasma concentration of chloramphenicol; Warfarin: prolong regular use with paracetamol increase risk of bleeding.

ADVERSE REACTIONS: Aceclofenac: Most common gastrointestinal (peptic ulcers, perforation or GI bleeding sometimes fatal, nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis, Crohn's disease, gastritis, pancreatitis); Hypersensitivity reactions (anaphylaxis, anaphylactoid reactions); serious skin/dermatological reactions (SJS, TEN); hematological reactions (thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia); oedema, hypertension and cardiac failure; dizziness; visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis; hepatic enzyme increased. **Paracetamol:** skin rash, lood dyscrasias including thrombocytopenia purpura, methaemoglobenaemia, agranulocytosis. **Trypsin-Chymotrypsin:** Hepatic damage and necrosis may precipitate arrhythmias, shivering during recovery. Rarely, chymotrypsin might cause an allergic reactions (symptoms include itching, shortness of breath, swelling of the lips or throat, shock, loss of consciousness) when taken by mouth.

MARKETED BY:

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(Additional information is available on request)