CHYMORAL PLUS

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

Abbreviated Prescribing information for CHYMORAL PLUS [Trypsin-Chymotrypsin with Diclofenac Potassium Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: *Trypsin-Chymotrypsin*: 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. Zymogens are then carried either into the bloodstream or the intestines where they are excreted or are converted by the process of proteolysis into the active enzymes that aid digestion. *Diclofenac*: Diclofenac is a non-steroidal agent with marked analgesic/anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase, (cyclo-oxygenase).

INDICATIONS: It is indicated for the treatment of mild acute edematous inflammatory painful conditions.

DOSAGE AND ADMINISTRATION: The dose and dose frequency of Chymoral Plus will be decided under the supervision of qualified physician.

CONTRAINDICATION: *Trypsin-Chymotrypsin*: Adjunctive therapy in management of inflammatory edema due to injury, surgery, infection or dental procedures, hypersensitivity to Chymoral ingredients or enzymes, Chymoral is contraindicated in patients with severe liver, kidney impairment, peptic ulcer, high vitreous pressure, and hypersensitivity. *Diclofenac*: Hypersensitivity to the active substance or any of the excipients, 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/haemorrhage (two or more distinct episodes of proven ulceration or bleeding), last trimester of pregnancy, hepatic failure, renal failure, established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease, like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.

WARNINGS & PRECAUTIONS: *Trypsin-Chymotrypsin*: Trypsin and Chymotrypsin should not be employed in patients with severe hepatic insufficiency and should be given cautiously to patient with renal damage or irregularities of blood clotting mechanism. To be used with caution during Lactation, or in the elderly, children, pregnancy (use only, if clearly indicated). *Diclofenac*: The concomitant use of Diclofenac with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight. If gastrointestinal bleeding or ulceration occurs in patients receiving diclofenac, the drug should be withdrawn. The elderly have increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRIs) or anti-platelet agents such as acetylsalicylic acid. If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), diclofenac should be discontinued. Monitoring of renal function is recommended as a precautionary measure when using diclofenac in such cases. Discontinuation therapy is usually followed by recovery to the pre-treatment state. Diclofenac should be discontinued at the first appearance of skin rash, mucosal lesions or any other signs of hypersensitivity. Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with diclofenac after careful consideration.

DRUG INTERACTIONS: *Trypsin-Chymotrypsin*: Systemic proteases may increase the effectiveness of herbal supplements. Chymotrypsin is also known to interact with alcohol. Chymotrypsin is known to interact with chloramphenicol. Trypsin chymotrypsin combination should not be administered concurrently with anticoagulants such as Coumadin, Heparin and clopidogrel. *Diclofenac*: If used concomitantly, diclofenac may increase plasma

concentrations of lithium. Monitoring of the serum lithium level is recommended. If used concomitantly, diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before treatment with methotrexate.

ADVERSE REACTIONS: *Trypsin-Chymotrypsin*: Hepatic damage and necrosis, arrhythmias, allergic reaction itching, shortness of breath, swelling of the lips or throat, shock, loss of consciousness, and death. *Diclofenac*: Thrombocytopenia, leucopoenia, anaemia, agranulocytosis, hypersensitivity, anaphylactic and anaphylactoid reactions, angioneurotic oedema, disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, headache, dizziness, somnolence, tiredness, paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident, confusion, hallucinations, disturbances of sensation, malaise, visual disturbance, vision blurred diplopia, optic neuritis, vertigo, tinnitus, hearing impaired, myocardial infarction, cardiac failure, palpitations, chest pain, hypertension, hypotension, vasculitis, asthma, pneumonitis, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer with or without bleeding or perforation, colitis, constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis, ischaemic colitis, transaminases increased, jaundice, liver disorder, rash, urticaria, bullous eruptions, eczema, erythema, erythema multiforme, stevens-johnson syndrome, toxic epidermal necrolysis, dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus, acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis, impotence, oedema.

MARKETED BY:

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Torrent Pharmaceuticals Limited.

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(Additional information is available on request)