ACYCLOSURE P

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

Abbreviated Prescribing information for ACYCLOSURE P (Aceclofenac and Paracetamol Tablets**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: The mode of action of aceclofenac is largely based on the inhibition to prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclo-oxygenase, which is involved in the production of prostaglandins and Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain impulse generation. Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however to be on a selective basis.

DOSAGE AND ADMINISTRATION: The film-coated tablet must be taken orally, swallowed whole with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake. Never change the dose of your medicine without talking to your doctor first.

CONTRAINDICATION:

Hypersensitivity to the active substance Aceclofenac and Paracetamol, or to any of the other excipients, Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding), NSAIDS are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. Asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, aspirin, or other nonsteroidal anti-inflammatory drugs, Hepatic failure and renal failure.

WARNINGS & PRECAUTIONS: Aceclofenac: The use of Aceclofenac with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided. Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Respiratory disorders, Cardiovascular, Renal and Hepatic Impairment, Renal, Hepatic, If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Aceclofenac should be discontinued. SLE and mixed connective tissue disease: In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis, Dermatological, Hypersensitivity reactions: As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug. Haematological: Aceclofenac may reversibly inhibit platelet aggregation. Long-term treatment. **Paracetamol:** Underlying liver disease increases the risk or paracetamol related liver damage, Patients should be advised to consult their doctor if their headaches become persistent, Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day, Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis. Use with caution in patients with glutathione depletion due to metabolic deficiencies.

DRUG INTERACTION: Aceclofenac: Other analgesics including cyclooxygenase-2 selective inhibitors, Anti-hypertensives, Diuretics, Cardiac glycosides, like digoxin, *Lithium*, Methotrexate, Mifepristone, Corticosteroids, Anti-coagulants, Quinolone antibiotics, Anti-

platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding, Ciclosporin, tacrolimus, Zidovudine, Antidiabetic agents **Paracetamol:** Cholestyramine, Metoclopramide and Domperidone, Warfarin, Chloramphenicol: Increased plasma concentration of chloramphenicol.

ADVERSE REACTIONS: Aceclofenac: dizziness, nausea (feeling sick), diarrhoea, increased liver enzymes in the blood, wind, inflammation or irritation of the lining of the stomach, constipation, vomiting, mouth ulcers , itching, rash, inflammation of the skin, raised circular red itchy, stinging or burning patches on the skin (hives), increase in blood urea levels, increase in blood creatinine levels, hypersensitivity (allergic reaction), problems with eyesight, heart failure, high blood pressure shortness of breath, bleeding from the stomach or bowel, stomach or bowel ulceration, depression, strange dreams, inability to sleep, tingling, pricking or numbness of skin, uncontrollable shaking, drowsiness, headaches , abnormal taste in the mouth, sensation of spinning when standing still, ringing in the ears, heart pounding or racing hot flushes, difficulty breathing, high pitched noise when breathing inflammation of the mouth, perforation of either the stomach, large intestine or bowel wall, worsening of colitis and Crohn's disease, inflammation of the pancreas injury of the liver (including hepatitis), yellowing of the skin (jaundice), spontaneous into the skin (appears as a rash), nephrotic syndrome: a condition which indicates kidney damage and includes large amounts of protein in the urine, low blood albumin levels, high blood cholesterol levels and swelling of the legs, feet or ankles, water retention and swelling, tiredness, leg cramps, increased blood alkaline phosphatase levels, weight gain, Other side effects that have been reported with this type of drug (NSAIDs) are: hallucinations, confusion, blurred, partial or complete loss of vision, painful movement of the eye, worsening of asthma, skin reaction to sunlight, inflammation of the kidneys, generally feeling unwell **Paracetamol:** Stop taking medication if you experience: Allergic reaction which may severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath, Skin rash or peeling or mouth ulcers, Breathing problem, Unexplained bruising or bleeding, Nausea, yellowing of the eyes and skin.

Manufactured by:
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(Additional information is available on request)