ZULU AT

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

Abbreviated Prescribing information for ZULU AT (Thiocolchicoside AND Aceclofenac**)**

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

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: ZULU AT contains Thiocolchicoside and Aceclofenac. Thiocolchicoside exhibits a selective affinity for the inhibitory gamma-aminobutyric acid and glycinergic receptors. 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.

DOSAGE AND ADMINISTRATION: ZULU AT tablets should be administered orally as directed by the Physician. Tablets should be swallowed whole and should not be chewed or crushed.

CONTRAINDICATION:

Thiocolchicoside: Hypersensitivity to Thiocolchicoside or to any of the excipients, pregnancy and lactation; in women of child bearing potential not using effective contraceptive

Aceclofenac: Hypersensitivity to Aceclofenac or to any of the excipients, Active, or history of recurrent peptic ulcer/haemorrhage. It is contraindicated in patients previously sensitive to aceclofenac or aspirin or other NSAIDs. It should not be administered to patients with active or suspected peptic ulcer or gastrointestinal bleeding and moderate to severe renal failure, heart failure and hepatic failure. Aceclofenac should also be administered with caution and under close medical surveillance to patients with congestive heart failure, significant risk factors for cardiovascular events and history of cerebrovascular bleeding.

WARNINGS & PRECAUTIONS:

Thiocolchicoside: Thiocolchicoside should not be used in patients with severe renal failure. In reported preclinical studies, one of thiocolchicoside metabolites (SL59.0955) induced aneuploidy at concentrations close to human exposure observed at doses 8 mg twice daily per os. Aneuploidy is reported as a risk factor for teratogenicity, embryofoetotoxicity/spontaneous abortion, cancer, and impaired male fertility. As a precautionary measure, use of the product at doses exceeding the recommended dose or long-term use should be avoided. Patients should be carefully informed about the potential risk of a possible pregnancy and about effective contraception measures to be followed.

Aceclofenac: Aceclofenac should be administered with caution to patients with symptoms indicative of gastrointestinal disorders, ulcerative colitis, Crohn's disease, hepatic porphyria, and Haematological abnormalities. Patients suffering from severe hepatic impairment must be monitored. Use in pregnancy & lactation: Pregnancy: There is no information on the use of Aceclofenac during pregnancy. Aceclofenac is contraindicated during the third trimester of pregnancy, unless there are compelling reasons for doing so. Aceclofenac should not be given to lactating mother unless potential benefits outweigh the risk to the fetus.

DRUG INTERACTION: Lithium and Digoxin: ZULU AT, like other NSAIDs, may increase plasma concentrations of lithium and digoxin. Diuretics: ZULU AT, like other NSAIDs, may inhibit the activity of diuretics. Anticoagulants: Like other NSAIDs, ZULU AT may enhance the activity of anticoagulants. Quinolones: Convulsion may occur due to an interaction between

quinolones and NSAIDs. Other NSAIDs and steroids: Concomitant therapy with aspirin, other NSAIDs and steroids may increase the frequency of side effects.

ADVERSE REACTIONS: Thrombocytopenia, leukopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis, Hypersensitivity, anaphylactic and anaphylactoid reactions, Headache, dizziness, Somnolence, drowsiness, tiredness, hypotension, Paraesthesia, memory impairment/disturbance, convulsion, flatulence, anorexia, Gastritis, gastrointestinal haemorrhage or bleeding, haematemesis, diarrhoea haemorrhagic/bloody, melaena, gastrointestinal ulcer, Stevens Johnson syndrome (SJS) and Toxic Epidermal.

Marketed BY:
TORRENT PHARMACEUTICALS LTD.
Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA
Torrent Pharmaceuticals Ltd.

IN/ZULU AT 4/8,100mg/APR-21/01/ABPI
(Additional information is available on request)