Diclogesic RR

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

Abbreviated Prescribing information for Diclogesic RR (Diclofenac Sodium Injection)

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

PHARMACOLOGICAL PROPERTIES: Diclofenac sodium is a non-steroidal agent with marked analgesic/anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase.

INDICATION: For acute painful conditions in post-operative pain, renal colic and acute exacerbation of gouty arthritis. (For Intramuscular (IM) and intravenous (IV) Use).

DOSAGE AND ADMINISTRATION: Adults: It should not be given for more than two days**. Intramuscular Injection:** One vial once (or in severe cases twice) daily. For Renal colic: One 75 mg dose which can be increased up to 150 mg. **Intravenous Injection:** It may be given as an intravenous bolus injection. For post-operative pain and acute renal colic: 75 mg should be injected intravenously. For prevention of post-operative pain, a loading dose of 25 mg to 50 mg administered as a 5 to 60 second intravenous bolus after surgery, followed by additional injections up to a maximum daily dosage of 150 mg. For elderly: the lowest effective dose should be used. Not recommended in children.

CONTRAINDICATION: Patients with known hypersensitivity of any component of this product. Active or history of recurrent peptic ulcer/hemorrhage, severe heart failure, renal failure, and hepatic failure, last trimester of pregnancy, History of gastrointestinal bleeding or perforation, history of asthma, Concomitant NSAID including cyclooxygenase-2 selective inhibitors or anticoagulant use, A history of haemorrhagic diathesis, Operations associated with a high risk of haemorrhage, asthma, renal impairment.

WARNINGS & PRECAUTIONS: **WARNINGS:** Elderly: increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. Patients with a history of GI toxicity should report any unusual abdominal symptoms. NSAIDs should be given with care to patients with a history of gastrointestinal disease. Systemic lupus erythematosus and mixed connective tissue disease: these patients have increased risk of aseptic meningitis. Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Allergic reactions, including anaphylactic/anaphylactoid reactions, can occur. Patients with renal impairment should not be
treated with Diclofenac sodium.

PRECAUTIONS: Patients with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics or those recovering from major surgery and the elderly, are at greatest risk of renal failure. If abnormal liver function tests persist or worsen, Diclofenac should be discontinued. Diclofenac may reversibly inhibit platelet aggregation. Not recommended for long term use. Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure. It may impair female fertility and is not recommended in women attempting to conceive.

DRUG INTERACTION: It can interact with Lithium and digoxin, Anticoagulants, Antidiabetic agents, Ciclosporin, Methotrexate, Quinolone antibiotics, Concomitant use of two or more NSAIDs or corticosteroids, Diuretics, Cardiac glycosides, Mifepristone, Anti-hypertensives, Cyclosporine, Phenytoin, Colestipol and Cholestyramine, Corticosteroids, Antiplatelet agents and selective serotonin reuptake inhibitors (SSRIs), Potent CYP2C9 inhibitors, Tacrolimus and Zidovudine.

ADVERSE REACTIONS: Nausea, Vomiting, Diarrhoea, Dyspepsia, Abdominal Pain, Flatulence, Anorexia, Headache, Dizziness or vertigo, Drowsiness, Tiredness, Dysgeusia, Oaraesthesia, Balance impairment, Aponia, Hypoaesthesia, Migraine, Speech disorder, or trismus, Pain, Chest pain/tightness, Malaise, Rigors, Bloody discharge, Pyrexia, Pain in jaw, Eyelid oedema, Eyelid pruritus, Increased lacrimation, or eye pain, Rashes or skin eruptions, Urticaria, Pruritus, or sweating increased, Oedema, Renal pain, Elevation of hepatic enzymes (ALT, AST), Liver function disorders, Neutrophilia, Hypersensitivity reactions, Respiratory

disorder NOS, or Rhinorrhoea, Haemorrhage, Phlebitis, Hypotension, Bradycardia, or flushing, Elevated creatine phosphokinase, Ketonuria, Haematuria, or Bilirubin in urine, Rreactions such as local pain and induration due to IM injection, Injection site necrosis (Nicolau syndrome), Thrombophlebitis due to IV injection, Increased risk of arterial thrombotic events.

MARKETED BY:

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(Additional information is available on request)