Basic Succinct Statement: VOVERAN® 1 ml AQ

Presentation: Diclofenac sodium: ampoules of 75 mg/1 ml for i.m, I.V use (inj.) **Indications:** For management of painful conditions in post-operative cases, rheumatoid arthritis and osteoarthritis. **Dosage and administration:** Dose to be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary. Adults- 1 or at the most 2 ampoules (i.m. or i.v.) daily as initial therapy for not more than 2 days. Ampoules must not be given as an i.v. bolus injection. Before i.v. infusion dilute contents of 1 ampoule with 100 to 500 mL of saline 0.9% or glucose 5% and buffering with sodium bicarbonate should be done. I. V administration should be done as slow infusion over 30min to 2hrs. Total maximum daily dose is 150 mg. The directions for intramuscular injection both for intradeltoid and intragluteal must be followed in order to avoid damage to a nerve or other tissue at the injection site. **Contraindications:** •Known hypersensitivity to the active substance or any of the other excipients. •Active gastric or intestinal ulcer, bleeding or perforation. •Last trimester of pregnancy. Hepatic and renal failure (GFR <15 mL/min/1.73 m2). •Severe cardiac failure. •Like other non-steroidal anti-inflammatory drugs (NSAIDs), Voveran 1ml is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs. **Warnings and precautions:** •Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. •Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. •Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents •Caution recommended in patients with ulcerative colitis or Crohn's disease. •Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. •Monitoring of blood counts recommended during prolonged treatment. •Monitoring recommended in patients with defects of haemostasis. •Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. •Special caution recommended for parenteral use in patients with bronchial asthma (INJ only). •Risks of serious allergic reactions. To be discontinued if these conditions occur. •Caution recommended in patients with impaired hepatic function (including porphyria). •Monitoring of liver function during prolonged treatment. •Beware of severe fluid retention and edema. •Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. •Avoid use with other systemic NSAIDs including COX-2 inhibitors. •May mask signs and symptoms of infection. **Pregnancy:** The use of diclofenac has not been studied in pregnancy; hence must not be used in first two trimesters of pregnancy unless the potential benefit to the mother outweighs the risk to the foetus. Avoid usage after 30 weeks of gestation. Not recommended in new born babies and children. **Lactation:** Like other NSAIDS, diclofenac passes into the breast milk in small amounts. Therefore should not be administered during breast feeding in order to avoid adverse effects in the infant. **Fertility:** Like other NSAIDS, diclofenac may impair female fertility; hence it should not be used in women attempting to conceive. **Elderly:** Caution is indicated on basic medical terms. **Drug Interactions:** •Monitoring of serum lithium or digoxin levels recommended if used concomitantly. •Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs.). •Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. •Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. •Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole), and CYP2C9 inducers (e.g. rifampicin). •Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. •Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. •Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. **Adverse Reactions:** Injection site reaction, injection site pain, injection site induration. Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, transaminases increased, rash. • Myocardial infarction, cardiac failure, chest pain, palpitations.• Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema, injection site necrosis.•Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment, blurred vision, diplopia, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/ hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, injection site abscess. **Packaging information:** 1 ml glass ampoule.

Note: For Further information, please write to Medical information cell, Branded Formulations, **Dr. Reddy's Laboratories Ltd.**, 7-1-27, Ameerpet Hyderabad-500 016. Toll free No.: 1800 425 0014, e-mail: customerservices@drreddys.com.

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Warning: Not for veterinary use.

For the use of a registered medical practitioner or a hospital or a laboratory only.

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