headache, dizziness, nervousness, tinnitus, depression, drowsiness and insomnia. Hypersensitivity reactions may occur occasionally and include fever and rashes. Hepatotoxicity and aseptic meningitis may also be hypersensitivity reactions. It can provoke bronchospasm in patients with asthma. It may cause cystitis and haematuria. It may also cause acute renal failure, interstitial nephritis, and nephrotic syndrome. Other adverse effects include anaemias, thrombocytopenia, neutropenia, eosinophilia, agranulocytosis, abnormalities in liver function tests, blurred vision, changes in visual colour perception, and toxic amblyopia. It should not be given to patients with active peptic ulceration. It should be given with care to the elderly, to patients with asthma or bronchospasm, bleeding disorders, cardio-vascular-disease, a history of peptic ulceration, and in liver or renal failure. Patients with congestive heart failure, cirrhosis, diuretic-induced volume depletion, or renal insufficiency are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis. Care is required in those who are also receiving coumarin anticoagulants. Patients who are sensitive to aspirin or other NSAID's should generally not be given diclofenac. Diclofenac should be discontinued in patients who experience blurred or diminished vision, or changes in colour vision. Patients with collagen disease may be at increased risk of developing aseptic meningitis. In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients. When given together with preparations containing lithium or digoxin, diclofenac sodium may raise their blood concentrations. Patients receiving long-term treatment with diclofenac should have periodic blood counts. Studies have demonstrated a pharmacokinetic interaction between diclofenac and salicylates when both are co-administered in anti-inflammatory doses.

KNOWN SYMPTOMS OF OVERDOSAGE AND ITS TREATMENT:

See "Side-effects and Special Precautions". Treatment is symptomatic and supportive.

IDENTIFICATION: Clear colourless, to a pale yellow solution.

PRESENTATION: A Clear colourless solution filled in 1 ml clear glass ampoules

STORAGE: Store in a cool ,dry &dark place . Protected from direct sunlight. Improper storage may be deteriorate the product.

Scan for Batch Certificate

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Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302 ●E-mail: info@americanremedies.in

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℞ Diclofenac Sodium Injection I.P.

AMERICAN Diclocan AQ

Injection

Composition :

Each ml contains

Diclofenac Sodium	I.P	75 mg
Benzyl alcohol	I.P	4%v/v
(as Preservative)		
Water for Injection	I.P.	q.s.

PHARMACOLOGICAL CLASSIFICATION:

Antirheumatics (anti-inflammatory agents)

DESCRIPTION : Diclofenac Sodium is sodium 2-[(2,6-dichloropheny1)-amino]phenylacetate.

PHARMACOLOGICAL ACTION:

Diclofenac sodium has analgesic, anti-inflammatory, anti-rheumatic, antipyretic activities. It is non steroidal. It is an inhibitor of cyclo-oxygenase. Diclofenac is metabolised in the liver to 4-hydroxydiclofenac and other hydroxylated forms, after glucoronidation and sulphation the metabolites are excreted in the urine (65%) and bile (35%).

INDICATIONS:

To be used as initial therapy for inflammatory and degenerative rheumatic diseases, as well as for painful conditions due to inflammation of non-rheumatic origin and acute attacks of gout.

CONTRA-INDICATIONS:

Patients with known hypersensitivity to diclofenac, or other non-steroidal anti-inflammatory medicines. Asthmatic patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylicacid, or other medicines with prostaglandin synthetase inhibiting activity. Diclofenac sodium is contra-indicated in patients with a history of active gastro-intestinal bleeding or peptic ulceration, or severe hepatic or renal impairment. Patients with porphyria. Safety during pregnancy and lactation has not been established.

WARNINGS:

Serious interactions have been reported after the use of methotrexate with diclofenac.

DOSAGE AND DIRECTIONS FOR USE:

Not intended for intravenous injection. Only for deep intragluteal injection into the upper quadrant. 75mg by intramuscular injection once daily or twice daily in severe cases; each injection should be given at a different site. In renal colic the intramuscular dose of 75 mg may be repeated once after 30 minutes if necessary. Diclofenac ampoules should not be given for more than a few (2) days. If necessary, treatment can be continued with oral therapy.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Gastro-intestinal disturbances; reactions range from abdominal discomfort, nausea and vomiting, and abdominal pain to serious gastro-intestinal bleeding or activation of peptic ulcer. CNS-related side-effects include