ANODYNE PLUS

DICLOFENAC SODIUM BP & LIDOCAINE USP

Compositions:
Anodyne Plus injection: Each 2 ml ampoule contains Diclofenac Sodium BP 75mg and Lidocaine Hydrochloride USP 20mg.

Pharmacology:
Anodyne Plus is a potent non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. It also has some uricosuric effect. Diclofenac inhibits cyclooxygenase activity with a reduction in the tissue production of prostaglandins.

Indications:
Anodyne Plus injection contains diclofenac sodium and is indicated in Rheumatoid arthritis, Osteoarthritis, Low back pain and other acute musculoskeletal disorders such as periarthritis (e.g. frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, strains and dislocations, ankylosing spondylitis, acute gout, Control of pain and inflammation in orthopaedic, dental and other minor surgery, Juvenile rheumatoid arthritis, postoperative pain, renal colic pain & other uses. Anodyne Plus injection also contains lidocaine which is a widely used local anesthetic. Therefore, the possibility pain at the injection site which is most likely to occur after intramuscular injection of normal diclofanac, is minimized if Anodyne Plus injection is used in the above indications.

Dosage And Administration:
Adults: By deep IM injection into the gluteal muscle, acute exacerbations and post-operative - One ampoule once daily (twice daily in severe cases) for max. of 2 days. Renal / ureteric colic: One ampoule once daily intramuscularly. A further ampoule may be administered after 30 minutes, if necessary. Maximum daily dose: Diclofenac 150 mg, Lidocaine 200mg. Children : In Juvenile chronic arthritis: 1-3 mg of diclofenac/kg body wt. daily in divided doses. Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, commensurate with age and physical status, or as prescribed by the physician.

Contraindications:
Active peptic ulcer; asthma, aspirin or any non-steroid anti-inflammatory induced allergy. Previous sensitivity to diclofenac sodium concomitant NSAID (intravenous use) or anticoagulant use (including low-dose heparin). Operations associated with a high risk of hemorrhage (intravenous use). Moderate or severe renal impairment (serum creatinine > 160 mmol. L-1), hypovolaemia or dehydration from any cause.

Warning And Precaution:
History of gastrointestinal lesions; impaired renal function; pregnancy & lactation; concurrent administration of plasma protein-bound drugs, lithium, beta-blockers or frusemide.

Side Effects:
Mild and infrequent gastro-intestinal discomfort, bleeding, nausea, vertigo, headache, hearing disturbances such as tinnitus; thrombocytopenia; hypersensitivity reactions.

Use in Pregnancy and Lactation:
Diclofenac should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. This type of drugs are not recommended during the last trimester of pregnancy. Very small quantities of diclofenac may be detected in breast milk, but no undesirable effects on the infant are to be expected. Since

no experience has been acquired with diclofenac in pregnancy or lactation, it is not recommended for use in these circumstances.

Drug Interaction:
Potential hazardous interactions with lithium, digoxin, diuretics, methotrexate.

Overdosage:
Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose. Patients should be managed by symptomatic and supportive care following a NSAID overdose. There are no specific antidotes. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large overdose (5 to 10 times the usual dose). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

Storage:
Store in a cool (below 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:
Each box contains 5 x 2's blister of 2 ml ampoules.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.