DYCLO Plus Inj.

(Diclofenac Sodium+Lignocaine Hydrochloride)

Composition:
Each 2ml ampoule contains:
Diclofenac Sodium BP..... 75mg.
Lignocaine Hydrochloride BP..... 20mg.

Description:
Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with marked analgesic and antipyretic properties. It also has some uricosuric effect. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis. Diclofenac may inhibit the synthesis of prostaglandins by inhibiting cyclooxygenase, an enzyme that catalyzes the formation of prostaglandin precursors (endoperoxides) from arachidonic acid.

Diclofenac is 99.7% plasma protein bound and plasma half-life for the terminal elimination phase is 1-2 hours. It also enters the synovial fluid, where maximum concentrations are measured 2-4 hours after the peak plasma values have been obtained. The apparent half-life for elimination from the synovial fluid is 3-6 hours.

Diclofenac is extensively metabolized to a range of phenolic compounds. About 60% of the administered dose is excreted via the kidneys in the form of metabolites and less than 1% in unchanged form. The remaining is excreted via the bile in metabolized form. Peak plasma concentration of diclofenac is achieved within half an hour following injection.

Lignocaine is the most widely used local anaesthetic drug. It acts more rapidly and is more stable than most other local anaesthetics. It is a very useful surface anaesthetic. Like other local anaesthetic, Lignocaine impairs the generation and conduction of the nerve impulses by slowing depolarization. Lignocaine is effectively absorbed from mucous membranes.

The onset of anaesthesia of Lignocaine Hydrochloride is more rapid and the duration of action is longer. A 1%-2% solution has duration of action of about 1-2 hours. Binding of Lignocaine to plasma proteins is variable and concentration dependent. Approximately 90% of a parenteral dose of Lignocaine is rapidly metabolized in the liver. Less than 10% of a dose is excreted unchanged in the urine.

Indications:
1) Rheumatoid Arthritis.
2) Osteoarthritis.
3) Low back pain and other acute musculoskeletal disorders such as periarthritis (e.g. Frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, strains and dislocations.
4) Ankylosing spondylitis.
5) Acute gout.
6) Acute trauma and fractures.
7) Control of pain and inflammation in orthopaedic, dental and other minor surgeries.
8) Juvenile chronic arthritis.
9) Postoperative pain.
10) Pain of renal colic.

Dyclo Plus Injection also contains lignocaine, which acts as a local anaesthetic. Therefore, the possibility of pain at the injection site, which is most likely to occur after intramuscular injection of normal diclofenac, is minimized if Dyclo Plus injection is used in the above indications.

Dosage and Administration:

- ***Adults:*** One ampoule once (or in severe cases, twice) daily by intramuscular injection. Renal colic: One ampoule once daily intramuscularly, a further ampoule may be administered after 30 minutes, if necessary.
  The recommended maximum daily dose of diclofenac and lignocaine is 150mg and 200mg respectively by any route.

- ***Children:*** In juvenile chronic arthritis, 1-3mg of diclofenac/kg body weight daily in divided doses.

- ***Elderly Patients:*** In elderly or debilitated patients, the lowest effective dosage is recommended, commensurate with age and physical status as prescribed by the physician.

Contraindications:

- Hypersensitivity to diclofenac.
- It is also contraindicated in those patients who are hypersensitive to local anaesthetics of the amide type, although the incidence is very rare.

Side Effects:

Side effects to diclofenac and Lignocaine injection are usually mild and transient. However, if serious side-effects occur, the injection should be discontinued. Gastrointestinal discomfort, nausea, diarrhoea and occasionally bleeding may occur. In very rare instances, injection site disorders may occur. In isolated cases, abscesses and local necrosis may occur. The adverse effects due to lignocaine mainly involve the CNS, are usually of short duration, and are dose related. The CNS reaction may be manifested by drowsiness, dizziness, disorientation, confusion, lightheadedness etc.

Precautions:

History of gastrointestinal ulceration, haematemesis or melaena, ulcerative colitis, Crohn's disease, bleeding diathesis or hematological abnormalities. Patients with severe hepatic, cardiac or renal insufficiency or the elderly should be kept under close surveillance. All patients who are receiving long term treatment with non-steroidal anti-inflammatory agents should be monitored as a precautionary measure (e.g. renal, hepatic function and blood counts).

Use in pregnancy & lactation:

It should not be prescribed during pregnancy and lactation.

Storage Conditions:

- Store below 30°C.
- Protect from heat and light.

Availability:

DYCLO Plus Injection: Pack of 20x2ml Ampoules.

Keep all medicines out of the reach of children.

Manufactured by :
Indus Pharma (Pvt.) Ltd.
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