Intafenac Plus® Injection

Diclofenac Sodium & Lidocaine Hydrochloride

1994

Presentation

Intafenac Plus® IM Injection: Each 2 ml injectable solution contains sterile Diclofenac Sodium BP 75 mg and Lidocaine Hydrochloride USP 20 mg.

Description

Diclofenac is a potent Non-Steroidal Anti-Inflammatory Drug (NSAID) with marked analgesic and antipyretic properties. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis. Diclofenac inhibits the synthesis of prostaglandins by inhibiting cycloxygenase enzyme. It also has some uricosuric effect.

Lidocaine 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, Lidocaine impairs the generation and conduction of the nerve impulses by slowing depolarization.

Indications and Uses

Intafenac Plus has got the following therapeutic uses:

- Postoperative pain
- Control of pain and inflammation in orthopaedic, dental and other minor surgery
- Acute trauma and fractures
- Low back pain and other acute musculoskeletal disorders such as periarthritis (e.g., frozen shoulder), tendonitis, tenosynovitis, bursitis, sprains, strains and dislocations.
- Renal colic pain
- Osteoarthritis
- Juvenile chronic arthritis
- Ankylosing spondylitis
- Acute gout
- Rheumatoid Arthritis
- Severe migraine attacks

Intafenac Plus injection also contains Lidocaine Hydrochloride, which acts as a local anaesthetic. Therefore, the possibility of pain at the injection site, which is most likely to occur after intramascular injection of normal Diclofenac, is minimized if Intafenac Plus injection is used.

Dosage and Administration

Intafenac Plus injection is intended for intramuscular injection.

Adults: The dosage is generally one 75 mg ampoule daily. In severe cases (e.g. colic) the daily dose can exceptionally be increased to two ampoules of 75 mg, separated by an interval of a few hours. Alternatively, one ampoule of 75 mg can be combined with other dosage forms (tablets, suppositories) up to a maximum daily dosage of 150 mg.

In migraine attacks, clinical experience is limited to initial use of 1 ampoule of 75 mg administered as soon as possible, followed by suppositories up to 100 mg on the same day if required. The total dosage should not exceed 175 mg on the first day.

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

Elderly patients: The lowest effective dosage is recommended, commensurate with age and physical status or as prescribed by the physician.

Side-effects

Side-effects of Diclofenac and Lidocaine injection are usually mild and transient. It is generally well tolerated. At the starting of the treatment, however, patients may sometimes complain of gastrointestinal discomfort, epigastric pain, eructation, nausea and Diarrhoea, headache and occasionally bleeding may occur. The adverse effects due to Lidocaine mainly involve the CNS, are usually of short duration, and are dose related. The CNS reaction may be manifested by drowsiness, dizziness, disorientation, confusion, lightheadness, etc

Contraindications

It is contra-indicated for those patients who are hypersensitive to Diclofenac. In patients with active or suspected peptic ulcer or gastrointestinal bleeding, or for those patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other NSAIDs possessing prostaglandin synthetase inhibitinig activity, it is also contraindicated.

Because of the presence of Lidocaine, it is also contraindicated for those patients who are hypersensitive to local anaesthetics of the amide type, although the incidence is very rare.

Precautions

History of gastrointestinal ulceration, haematemesis or melaena, ulcerative colitis, Crohn's disease, bleeding diathesis or haematological 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 NSAID agents should be monitored as a precautionary measure (e.g., renal, hepatic function and blood counts).

Drug interactions

Intafenac Plus may interact with following drugs: Lithium, digoxin, diuretics, other NSAIDs, anticoagulants, antidiabetics, methotrexate, cyclosporine, quinolone antibacterials.

Use in Pregnancy and Lactation

Pregnancy: It should not be prescribed during pregnancy, unless there are compelling reasons for doing so. The lowest effective dosage should be used. These types of drugs are not recommended during the last trimester of pregnancy.

Lactation: Very small quantities of Diclofenac may be detected in breast milk, but no undesirable effects on the infant are to be expected.

Storage conditions

Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Overdosage

There is no typical clinical picture associated with an overdosage of Diclofenac. Specific measures such as forced diuresis, dialysis or haemoperfusion are unlikely to be helpful in eliminating NSAIDs because of their high protein-binding rate and extensive metabolism.

Commercial Pack

Intafenac Plus® IM Injection: Each box contains 10 ampoules of 2 ml.

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Dhamrai Unit, Dhaka, Bangladesh
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