Bosch

For Medical Professional only

DIFAM Plus INJECTION IM

ڈائیفام پلس
انجکشن انٹرا مسکولر

(Diclofenac Sodium + Lidocaine HCl U.S.P.)

75mg/20mg per 2ml

(Product Specs.: M.S.)

Presentation:
Difam Plus IM injection: Each 2 ml ampoule contains Diclofenac Sodium USP 75 mg and Lidocaine Hydrochloride USP 20 mg.

Description:
Diclofenac Sodium is a potent non-steroidal anti-inflammatory drug (NSAID) with marked analgesic and antipyretic properties. It also has some uricosuric effects. The action of Diclofenac appeared to be associated with the inhibition of prostaglandin synthesis. Diclofenac may inhibit synthesis of prostaglandins by inhibiting cyclooxygenase, an enzyme that catalyses the formation of prostaglandin precursors from arachidonic acid. Peak plasma concentration is achieved within half an hour following injection. 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 anaesthetics, Lidocaine impairs the generation and conduction of nerve impulses by slowing depolarization. The onset of anaesthesia of Lidocaine Hydrochloride is more rapid and the duration is 1-2 hours.

Indications
The injection contains Diclofenac Sodium that is used to relief all grades of pain and inflammation in a wide range of conditions including:

a) Arthritic conditions such as rheumatoid arthritis, osteoarthritis, juvenile chronic arthritis, ankylosing spondylitis, acute gout.
b) Acute musculoskeletal disorders such as periarthritis (e.g., Frozen shoulder), tendinitis, tenosynovitis, bursitis.
c) Other painful conditions resulting from trauma including, fracture, low back pain, sprains, strains, dislocations, control of pain and inflammation in orthopaedic, dental and other minor surgeries, postoperative pain, pain of renal colic etc.

The injection also contains Lidocaine which acts as a local anaesthetic. Therefore the possibility of pain at the injection site, which is most likely to occur after intramuscular injection, is minimized if the Difam Plus (Lidocaine containing) injection is used in the above indications.

Dosage and Administration
Adult: One ampoule once (or in severe cases, twice) daily by intramuscular injection.

Renal colic: One ampoule once daily intramuscularly. A second dose may be administered after 30 minutes if necessary.

Children: In Juvenile chronic arthritis, 1-3 mg of Diclofenac Sodium per 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, or as prescribed by the physician.

Adverse Effects:
Side effects to Diclofenac Sodium and Lidocaine 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 disorder may occur. In isolated cases, abscesses and local necrosis may occur. The adverse effects due to Lidocaine mainly involve the CNS, are usually of short duration, and are dose related. The CNS reactions may be manifested by drowsiness, dizziness, disorientation, confusion, lightheadedness, etc.

Contraindications:
It is contraindicated 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 inhibiting activity, Diclofenac is also contraindicated. Because of the presence of Lidocaine, Difam Plus injection is also contraindicated for those patients who are hypersensitive to local anaesthetics of the amide type, although the incidence is very rare.

Drug Interactions

Lithium and Digoxin: Diclofenac may increase plasma concentrations of Lithium and Digoxin.

Anticoagulants: There are isolated reports of an increased risk of haemorrhage with the combined use of Diclofenac and anticoagulant therapy, although clinical investigations do not appear to indicate any influence on anticoagulant effect.

Antidiabetic agents: Clinical studies have shown that Diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect.

Cyclosporin: Cases of nephrotoxicity have been reported in patients receiving Cyclosporin and Diclofenac concomitantly.

Methotrexate: Cases of serious toxicity have been reported when Methotrexate and NSAIDs are given within 24 hours of each other.

Quinolone antimicrobials: Convulsions may occur due to an interaction between quinolones and NSAIDs. Therefore, caution should be exercised when considering concomitant therapy of NSAIDs and quinolones. Other NSAIDs and steroids: Co-administration of Diclofenac with other systemic NSAIDs and steroids may increase the frequency of unwanted effects. With Aspirin, the plasma levels of each are lowered, although no clinical significance is known.

Diuretics: Various NSAIDs are liable to inhibit the activity of diuretics. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels. So, serum potassium should be monitored.

Precautions

Renal: Patients with severe hepatic, cardiac or renal insufficiency or the elderly should be kept under close observation, since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function should be monitored. Hepatic: If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Diclofenac should be discontinued. All patients who are receiving long term treatment with NSAIDs should be monitored as a precautionary measure (e.g., renal, hepatic function and blood counts).

Use in 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.

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

Overdosage: Symptoms following acute NSAIDs 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.

Commercial Pack

Difam Plus IM injection:
Each box containing 5X2ml ampoules.

Direction

Protected from light, store in a cool and dry place at temperature 15-25^{o}C.
Keep out of reach of children.
For suspected adverse drug reaction for BOSCH products, report at ade@bosch-pharma.com

WARNING: To be sold on prescription of a registered medical practitioner only.

ہدایات برائے استعمال:

صرف انٹرامسکولر استعمال کے لئے۔
روشنی سے محفوظ ٹھنڈی اور خشک جگہ پر ۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت پر رکھیں۔
بچوں کی پہنچ سے دُور رکھیں۔
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
انتباہ : صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لئے۔

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ISO 9001:2015 Certified Company