Only for the use of Medical Professionals

Mobifen®

Diclofenac Sodium

Description

Mobifen®is a preparation of diclofenac Sodium. It is a non-steroidal anti-inflammatory agent with marked analgesic, anti-inflammatory and antipyretic properties. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis by inhibiting cycloxygenase enzyme.

Indication and Uses

Mobifen® tablet and capsule are indicated in rheumatoid arthritis, osteoarthritis, low back pain and other acute musculo-skeletal disorders such as frozen shoulder, tendinitis, tenosynovitis, bursitis, sprain, strain and dislocation, ankylosing spondylitis, acute gout, pain in orthopaedics, dental and other minor surgery.
Mobifen® plus Injection is indicated in acute exacerbation of rheumatoid arthritis and osteoarthritis, acute back pain, acute gout, postoperative pain, relief of pain in acute trauma and fractures, renal and severe migraine attack.

Dosage and Administration

Mobifen® 50mg enteric coated tablet:

Adults: 75 to 150mg daily in 2 to 3 divided doses, preferably after food. Dose should be reduced in long term use.

Children: 1 t0 3mg/kg body weight daily in divided doses.

Mobifen® 75mg and 100mg SR capsule:

Adults: Mobifen® SR 100mg capsule once daily or Mobifen® SR 75mg capsule one or twice daily, taken whole with liquid, preferably at meal times.

Childredn: Mobifen® SR is not recommended for children.

Elderly patients: In elderly or debilitated patients, the lowest effective dosage is recommended, although the pharmacokinetics of Diclofenac Sodium is not impaired to any clinically relevant extent in elderly patients.

Mobifen® Plus injection:

Adults: The dosage is generally one ampoule once (or in severe cases, twice) daily intramuscularly.
In migraine attacks initially 1 ampoule of 75mg administered as soon as possible.
In 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 is 150mg, by any route.
The recommended maximum daily dose of lidocaine is 200mg.

Children: In juvenile chronic arthritis, 1 to 2 3mg/kg body weight daily in divided doses.

Elderly patients: In elderly or debilitated patients, the lowest effective dosages is recommended, commensurate with age and physical status.

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 is not recommended during the last trimester of pregnancy. Very small quantities of Diclofenac may be detected in breast milk, but no undersirable effects on the infant are to be expected.

Side Effects

Side-effects to Diclofenac are usually mild and transient. At the starting of the treatment patients may sometimes complain of gastrointestinal discomfort, epigastric pain, eructation, nausea and diarrhoea, headach 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 lidocaine mainly involve the CNS, are usually of short duration, and are does relater.

Contraindications

Diclofenac 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 inhibiting activity, it is also contraindicated.

Because of the presence of lidocaine, Mobife[@] Plus injection is also contra-indicated for those patients who are hypersensitive to local anaesthetics of the amide type, although the incidence is very rare. In patients with Adams-stokes syndrome or with severe degrees of SA, AV or intraventricular heart block in the absence of an artificial pacemaker, and for those patients who are hypersensitive to any of the excipients use in the formulation (sodium glycol), this injection is also contra-indicated.

Precautions

Patients with a history of peptic ulcer, heamatemesis, melaena, bleeding diathesis or with severe hepatic or renal insufficiency should be kept under close surveillance. If abnormal liver function tests persist or worsen, clinical signs and symptoms consistent with liver disease or if other manifestations occur (eosinophilia, rash), Mobifen should be discontinued. Use of Diclofenac in patients with hepatic porphyria may trigger an attack.

Drug interactions

Diclofenac may increase plasma concentrations of lithium and digoxin but on clinical signs of overdosage in such cases have yet been encountered.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light.

Presentation

Mobifen[@] 50mg tablet : each tablet contains Diclofenac sodium BP 50mg.

Mobifen[@] SR 75mg Capsule **:** Each capsule contains Diclofenc Sodium BP 75mg sustain release pellets.

Mobifen[@] SR 100mg Capsule **:** Each capsule contains Diclofenac Sodium BP 100mg sustain releases pellets.

Mobifen[@] 50 Plus Injection **:** Each 2ml ampoule contains Diclofenac Sodium Bp 75mg and Lidocaine Hydrochloride USP 20mg.

Package Quantities

Mobifen[@] 50mg Tablet : Carton of 100 tablets in Alu-PVC blister.

Mobifen[@] 50 SR 75mg Capsule : Carton of 100 capsules in Alu- PVC blister.

Mobifen[@] 50 SR 100mg Capsule : Carton of 100 capsules in Alu-PVC blister.

Mobifen[@] pluse Injection : Carton of 10 ampoules.

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