Vurdon Plus

Diclofenac Sodium BP &
Lidocaine Hydrochloride USP

COMPOSITION

Each 2 ml ampoule contains sterile solution of Diclofenac Sodium BP 75 mg and Lidocaine Hydrochloride USP 20 mg.

PHARMACOLOGY

Diclofenac Sodium is a non-steroidal drug with marked analgesic/anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase, (cyclo-oxygenase). When used concomitantly with opioids for the management of postoperative pain, it often reduces the need for opioids. Lidocaine Hydrochloride stabilises the neuronal membrane by inhibiting the ionic fluxes required to initiate and conduct impulses, thereby affecting local anaesthetic action.

INDICATION

This is effective in acute forms of pain, including renal colic, exacerbations of osteoarthritis and rheumatoid arthritis, acute back pain, acute gout, acute trauma and fractures and postoperative pain.
Lidocaine Hydrochloride is used along with Diclofenac Sodium for local anaesthesia.

DOSAGE AND ADMINISTRATION

One ampoule once (in severe cases twice) daily for adults intramuscularly by deep intragluteal injection into the upper outer quadrant. If two injections daily are required it is advised that the alternative buttock be used for the second injection. Alternatively, one ampoule of 75 mg can be combined with other dosage forms (tablets or suppositories) up to the maximum daily dosage of 150 mg.

In renal colic, one 75 mg ampoule intramuscularly is recommended. A further ampoule may be administered after 30 minutes if necessary. The recommended maximum daily dose is 150 mg.

In elderly patients, the lowest effective dosage is recommended and the patient should be monitored for GI bleeding during NSAID therapy.

It should not be given for more than two days; if necessary, treatment can be continued with tablets or suppositories.

Intramuscular injection must be adhered to avoid damaging a nerve or other tissue at the injection site.

CONTRAINDICATION

It is contraindicated in the following states:
- Hypersensitivity to the active substances, or any of the excipients.
- Active gastric or intestinal ulcer, bleeding or perforation.
- History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy.
- Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct).
- Hepatic failure
- Renal failure
- Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by Ibuprofen, Acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs.

WARNING & PRECAUTION

- The lowest effective dose be used in frail elderly patients or those with a low body weight. As with other non-steroidal anti-inflammatory drugs including Diclofenac Sodium, allergic reactions (including anaphylactic/anaphylactoid reactions) can also occur without earlier exposure to the drug. Hypersensitivity reactions can also progress to Kounis syndrome.
- Like other NSAIDs, Diclofenac Sodium may mask the signs and symptoms of the infection due to its pharmacodynamic properties.
- If gastrointestinal bleeding or ulceration occurs, the drug should be withdrawn. As with all NSAIDs, including Diclofenac Sodium, close medical surveillance is imperative and particular caution should be exercised when prescribing Diclofenac Sodium in patients with symptoms indicative of gastrointestinal disorders, or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation.
- If abnormal liver function tests persist or worsen, it should be discontinued. Hepatitis may occur with Diclofenac Sodium without prodromal symptoms.
- Fluid retention and edema have been reported in association with NSAID therapy, including Diclofenac Sodium.
- Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs.
- In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders, there may be an increased risk of aseptic meningitis.
- Patients with congestive heart failure (NYHA-I) or patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidemia, diabetes mellitus, smoking) should only be treated with diclofenac after careful consideration.
- During prolonged treatment with Diclofenac Sodium, as with other NSAIDs, monitoring of the blood count is recommended.
- In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations, Quincke's edema or urticaria are more frequent than in other patients.
- Injection site reactions have been reported after the administration of Diclofenac Sodium Intramuscularly, including injection site necrosis and embolia cutis medicamentosa (Nicolau syndrome).

SIDE EFFECT

Side effects are usually mild and transient. However, if serious side-effects occur, Diclofenac Sodium should be discontinued. Occasionally headache, dizziness, vertigo, epigastric pain, nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, anorexia, transaminases increased, rash, injection site reaction, injection site pain and injection site induration may occur.

USE IN PREGNANCY & LACTATION

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and or cardiac malformation and gastroschisis after the use of a prostaglandin synthesis inhibitor in early pregnancy. Therefore, during the first and second trimesters of dose should be kept as low and the duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to Diclofenac Sodium for several days from gestational week 20 onward. It should be discontinued if oligohydramnios or ductus arteriosus constriction is found. During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to cardiopulmonary toxicity (premature constriction/closure of the ductus arteriosus and pulmonary hypertension) and renal dysfunction.

USE IN CHILDREN AND ADOLESCENTS

Not recommended.

DRUG INTERACTION

Lithium: May increase plasma concentrations of lithium.
Digoxin: May raise plasma concentrations of digoxin.
Diuretics and antihypertensive agents: Should be administered with caution and patients, especially the elderly.
Potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim: May be associated with increased serum potassium levels.
Anticoagulants and anti-platelet agents: Could increase the risk of bleeding.
Other NSAIDs including cyclooxygenase-2-selective inhibitors and corticosteroids: May increase the risk of gastrointestinal bleeding or ulceration.
Selective serotonin reuptake inhibitors (SSRIs): May increase the risk of gastrointestinal bleeding.
Antidiabetics: Monitoring the blood glucose level is recommended.
Methotrexate: Increasing methotrexate levels.
Ciclosporin: May increase the nephrotoxicity of ciclosporin.
Tacrolimus: May increase the risk of nephrotoxicity.
Quinolone antibacterials: Convulsions may occur.
Phenytoin: Monitoring of phenytoin plasma concentration is recommended.
Colestipol and cholestyramine: Can induce a delay or decrease in absorption of diclofenac.
Cardiac glycosides: May exacerbate cardiac failure.
Mifepristone: Can reduce the effect of mifepristone.
Potent CYP2C9 inhibitors: Could result in a significant increase in peak plasma concentrations and exposure to diclofenac.

OVERDOSAGE

Overdosage can cause symptoms such as headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, diarrhoea, dizziness, disorientation, excitation, coma, drowsiness, tinnitus, fainting or convulsions. In the case of significant poisoning acute renal failure and liver damage are possible. Patients should be treated symptomatically as required.

STORAGE

Store below 30°C temperature in a cool and dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Each box contains 10 ampoules in Alu-PVC blister pack.

14020000386/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.