Volmax® SR

Diclofenac Sodium USP 100 mg Sustained Release Capsule

DESCRIPTION

Volmax® SR capsule is a preparation of diclofenac sodium. It is a non-steroidal agent with marked analgesic/anti-inflammatory properties. It is an inhibitor of prostaglandin synthetase (cyclo-oxygenase).

INDICATIONS

Volmax® SR capsule is indicated for the treatment of:

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism
- Post-traumatic and post-operative pain, inflammation and swelling (eg: following dental or orthopaedic surgery)
- Painful and/or inflammatory conditions in gynaecology (eg: primary dysmenorrhoea or adnexitis)

DOSAGE AND ADMINISTRATION

Adults:

The recommended daily dose is 100-200 mg in 1 or 2 divided doses. In milder cases, as well as for long-term therapy, 100 mg daily is usually sufficient.

Dosage should be taken preferably before meals.

CONTRAINDICATIONS

- Known hypersensitivity to the active substance, diclofenac sodium
- Active gastric or intestinal ulcer, bleeding or perforation
- Last trimester of pregnancy
- Severe hepatic, renal or cardiac failure
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac sodium is also contraindicated in patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.

SIDE-EFFECTS

The side effects of diclofenac correspond to those from ibuprofen, compared with other non-opioid pain relievers means somewhat to be better compatible.

USE IN PREGNANCY AND LACTATION

The use of diclofenac in pregnant women has not been studied. Therefore, diclofenac should not be used during the first two trimesters of pregnancy unless the potential benefit to the mother outweighs the risk to the foetus. As with other NSAIDs, use during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus. Animal studies have not shown any directly or indirectly harmful effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Like other NSAIDs, diclofenac passes into the breast milk in small amounts. Therefore, diclofenac should not be administered during breast-feeding in order to avoid adverse effects in the infant.

OVERDOSE

Management of acute poisoning with NSAIDs essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder and respiratory depression. Special measures such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to the high protein binding and extensive metabolism. Activated charcoal may be considered after ingestion of a potentially toxic overdose and gastric decontamination (e.g. vomiting, gastric lavage) after ingestion of a potentially life-threatening overdose.

PRECAUTIONS

Renal:

As fluid retention and edema have been reported in association with NSAID therapy, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion from any cause (eg: before or after major surgery). Monitoring of renal function is recommended as a precautionary measure when using diclofenac in such cases. Discontinuation of therapy is usually followed by recovery to the pre-treatment state.

Hepatic:

As with other NSAIDs, values of one or more liver enzymes may increase. During prolonged treatment with diclofenac, regular monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (eg: eosinophilia, rash), diclofenac should be discontinued. Hepatitis may occur without prodromal symptoms.

Caution is called for when using diclofenac in patients with hepatic porphyria, since it may trigger an attack.

Haematological:

During prolonged treatment with diclofenac, as with other NSAIDs, monitoring of the blood count is recommended.

Like other NSAIDs, diclofenac may temporarily inhibit platelet aggregation. Patients with defects of haemostasis should be carefully monitored.

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 NSAID 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.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Volmax® SR capsule : Box containing 6 strips of 10 capsules each. Each sustained release capsule contains Diclofenac sodium USP 100 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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