

# VOLTAC-K Film Coated Tablets



- Caution is called for when using diclofenac in patients with hepatic porphyria, impaired cardiac, congestive heart failure (NYHA-I), or renal failure.

- Caution is recommended when using diclofenac after gastro-intestinal surgery.

- In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

- Patients with defects of haemostasis, bleeding diathesis or haematological abnormalities should be carefully monitored.

## **Pregnancy & Lactation:**

**Pregnancy:** Pregnancy Category: C. Use of NSAIDs, including VOLTAC-K, during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus.

**Lactation:** Diclofenac passes into breast milk in small amounts. Therefore, Diclofenac should not be administered during breast feeding in order to avoid undesirable effects in the infant.

**Drug Interactions:** Diclofenac may raise plasma concentrations of lithium, phenytoin, methotrexate and Digoxin.

Diuretics and Anti-hypertensive agents: concomitant use of diclofenac with diuretics or antihypertensive agents may cause a decrease in their antihypertensive effect.

Drugs known to cause hyperkalemia: Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels. Anticoagulants: concomitant administration with diclofenac could increase the risk of bleeding.

Other NSAIDs, selective serotonin reuptake inhibitors (SSRIs) and corticosteroids: Co-administration with diclofenac may increase the risk of gastrointestinal bleeding or ulceration.

Ciclosporin: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Colestipol and cholestyramine: These agents can decrease the absorption of diclofenac.

## **Side Effects:**

Common side effects: Headache, dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased and rash. Uncommon and rare side effects: Hypersensitivity, anaphylactic and anaphylactoid reactions, somnolence, gastritis, gastrointestinal haemorrhage, haematemesis

cardiac failure, palpitations, chest pain and dyspnoea.

**Driving & using machines:** Patients who experience visual disturbances, dizziness, vertigo, somnolence while taking VOLTAC-K should refrain from driving or operate machinery.

**Dosage & Administration:** It is recommended that the tablets be taken with fluid, preferably with or after food.

**Adults:** The recommended daily dose is 100 -150mg in two or three divided doses. For milder cases, 75-100 mg daily in two or three divided doses is usually sufficient.

In migraine an initial dose of 50mg should be taken at the first signs of an impending attack.

In cases where the regression of symptoms two hours after the first dose is not sufficient, an additional dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4-6 hours, not exceeding a total dose of 200 mg per day.

**Paediatric population:** For children over 14 years of age, the recommended daily dose is 75-100mg in two or three divided doses. Diclofenac Potassium Tablets are not recommended for children under 14 years of age.

**Overdose:** Symptoms following acute NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting and epigastric pain, gastrointestinal bleeding can occur but very rarely, hypertension, acute renal failure, respiratory depression and coma.

Management: Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose. Special measures such as forced diuresis, dialysis are probably of no help in eliminating NSAIDs, including diclofenac, due to high protein binding and extensive metabolism.

**Storage:** Keep out of reach of children. Store below 30°C. Store in the original package

**Packaging:** Each VOLTAC-K carton box contains 20 Film Coated tablets in two blister strips.

**Composition:** Each VOLTAC-K Film Coated tablet contains:

Diclofenac Potassium 50 mg.

**Mechanism of Action:** Diclofenac potassium belongs to the family of non-steroidal anti-inflammatory drugs (NSAIDs), which have anti-inflammatory, analgesic and antipyretic effects.

The mechanism of action of diclofenac potassium is similar to that of other NSAIDs, which competitively inhibit the cyclooxygenase enzymes COX-1 and COX-2 and thus the synthesis of prostaglandins.

**Pharmacokinetics:** Diclofenac is rapidly and completely absorbed from the gastrointestinal tract but is subject to first-pass metabolism. The plasma concentrations show a linear relationship to the size of the dose. Diclofenac is highly bound to plasma proteins (99.7%), chiefly albumin. Approximately 60% of the administered dose is excreted via the kidneys in the form of metabolites and less than 1% in unchanged form. The rest is eliminated as metabolites through the bile in the faeces.

**Indications: VOLTAC-K** indicated:

- For relief of mild to moderate pain (e.g., Migraine attacks, fractures, acute gout, dental and other minor surgery).

- For treatment of primary dysmenorrhoea

- For relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis.

- For treatment of acute musculo-skeletal disorders and trauma such as peri-arthritis (especially frozen shoulder), tendinitis, tenosynovitis, bursitis, sprains, Joint dislocation and muscle strain.

## **Contraindications:**

- Hypersensitivity to the active substance or any of the excipients.

- Active, gastric or intestinal ulcer, bleeding or perforation.

- History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy.

- Hepatic failure and renal failure.

- Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

- Patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis.

## **Warnings & Precautions:**

- Use the lowest effective dose to control the condition being treated.

- Allergic reactions including anaphylaxis have been reported with diclofenac.

\*A medication is a product which affects your health, and its consumption contrary to instructions is dangerous for you.  
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.  
- The doctor and the pharmacist experts in medicine, it's benefits and risks.  
- Do not expect the same prescription without consulting your doctor.  
KEEP THE MEDICAMENTS OUT OF REACH OF CHILDREN  
Council of Arab Health Ministries, Union of Arab Pharmacies

Reva Pharmaceutical Industry - Syria

