DIFSOM-P TABLETS

(Diclofenac Potassium 50 mg)

COMPOSITION

Each tablet contains Diclofenac Potassium 50 mg. Excipients: according to the approved formulation.

DESCRIPTION

Difsom-P contains diclofenac potassium, a non-steroidal anti-inflammatory drug (NSAID) with analgesic, anti-inflammatory and antipyretic activity.

CLINICAL PHARMACOLOGY

Diclofenac inhibits cyclo-oxygenase (COX) activity and prostaglandin synthesis. The potassium salt is used in oral formulations for relief of pain and inflammation. Oral diclofenac is absorbed systemically, is highly protein bound, metabolised mainly in the liver and eliminated as metabolites in urine and bile.

INDICATIONS

Symptomatic relief of mild to moderate pain; primary dysmenorrhoea; signs and symptoms of osteoarthritis and rheumatoid arthritis. Other local approvals may include acute musculoskeletal pain and migraine. Use only for indications in the locally approved product information.

DOSAGE AND ADMINISTRATION

Oral use. Use the lowest effective dose for the shortest duration. For standard immediate-release diclofenac potassium 50 mg tablets, reference adult regimens include: pain or primary dysmenorrhoea - 50 mg three times daily; osteoarthritis - 100-150 mg/day in divided doses; rheumatoid arthritis - 150-200 mg/day in divided doses. Dose and duration must be individualised by the prescriber. Do not assume these regimens apply to modified-release tablets.

METHOD OF ADMINISTRATION

Swallow tablets with water. Administration with food may help gastrointestinal tolerability, but may delay onset of action. Follow the prescriber's instructions. Do not exceed the prescribed dose or combine with other NSAIDs without medical advice.

CONTRAINDICATIONS

Hypersensitivity to diclofenac or any excipient; previous asthma, urticaria or allergic-type reaction after aspirin or another NSAID; use in the setting of coronary artery bypass graft (CABG) surgery. Also avoid in active gastrointestinal ulceration or bleeding, and in patients with severe cardiac, hepatic or renal disease, according to applicable local labeling.

SERIOUS WARNINGS

CARDIOVASCULAR: NSAIDs can increase risk of serious thrombotic events including myocardial infarction and stroke, potentially fatal; risk may arise early and increase with dose or duration.

GASTROINTESTINAL: ulceration, bleeding and perforation may occur at any time, sometimes without warning and may be fatal. Elderly patients and those with previous ulcer or gastrointestinal bleeding are at higher risk.

PRECAUTIONS

Use cautiously in hypertension, heart failure, fluid retention, impaired kidney or liver function, asthma, dehydration and in elderly patients. Monitor blood pressure, renal and liver function, and blood counts during prolonged treatment when clinically indicated. Discontinue if bleeding, persistent abdominal pain, jaundice, severe rash, facial swelling, wheezing or chest pain occurs. Serious skin reactions including Stevens-Johnson syndrome may occur.

DRUG INTERACTIONS

Other NSAIDs or aspirin increase adverse effects. Anticoagulants, antiplatelet drugs, SSRIs and corticosteroids increase bleeding risk. ACE inhibitors, ARBs and diuretics may increase renal risk or reduce antihypertensive effect. Diclofenac may increase lithium, digoxin or methotrexate toxicity; ciclosporin and tacrolimus increase kidney risk. Discuss all concomitant medicines with a physician.

PREGNANCY

Avoid NSAIDs from about 20 weeks of pregnancy unless specifically directed by a clinician because of risk of fetal kidney dysfunction and oligohydramnios. Avoid at about 30 weeks and later because of risk of premature closure of the fetal ductus arteriosus. Diclofenac may impair female fertility; consider withdrawal if trying to conceive.

LACTATION

Small amounts of diclofenac may pass into breast milk. A clinician should weigh potential benefit and infant risk before use during breastfeeding.

PEDIATRIC AND GERIATRIC USE

Use in children only if specifically supported by the locally approved formulation and prescribed dosage. Older adults have increased risk of gastrointestinal, cardiovascular and renal complications; use the lowest effective dose for the shortest duration.

ADVERSE REACTIONS

Common: abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, flatulence, headache, dizziness, oedema and rash. Serious: gastrointestinal bleeding or perforation, kidney injury, hepatic injury, increased blood pressure, heart attack, stroke, anaphylaxis and severe skin reactions. Stop treatment and seek urgent care if serious symptoms occur.

OVERDOSAGE

Overdose may cause nausea, vomiting, abdominal pain, gastrointestinal bleeding, drowsiness, dizziness, seizures, renal impairment and metabolic disturbances. Seek emergency medical attention. Treatment is supportive and symptomatic; there is no specific antidote. Do not induce vomiting unless directed by a healthcare professional.

EFFECTS ON DRIVING

Dizziness, drowsiness or visual disturbance may occur. Avoid driving or operating machinery if affected.

STORAGE CONDITIONS

Store in a dry place, protected from excessive heat and moisture, according to approved pack labeling. Keep out of reach of children.

PRESENTATION

Difsom-P Tablets 50 mg: 2 x 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.