VCAM TABLETS

Meloxicam 7.5 mg and 15 mg
Oral tablets | Pack size: 10 tablets

COMPOSITION

Each 7.5 mg tablet contains Meloxicam 7.5 mg. Each 15 mg tablet contains Meloxicam 15 mg. Excipients: according to the approved Vcam product formulation.

THERAPEUTIC CLASS

Non-steroidal anti-inflammatory drug (NSAID); preferential cyclo-oxygenase-2 inhibitor. Analgesic and anti-inflammatory agent.

PHARMACOLOGY

Meloxicam inhibits prostaglandin synthesis through cyclo-oxygenase inhibition, producing anti-inflammatory, analgesic and antipyretic effects. Its COX-2 preference does not eliminate gastrointestinal, cardiovascular or renal risks.

INDICATIONS

Relief of signs and symptoms of osteoarthritis and rheumatoid arthritis. Certain approved products are indicated for juvenile rheumatoid arthritis in patients weighing at least 60 kg; confirm local authorization before paediatric use.

DOSAGE AND ADMINISTRATION

Adults with osteoarthritis or rheumatoid arthritis: Initially 7.5 mg orally once daily. Depending on response, may increase to 15 mg once daily. **Maximum adult dose: 15 mg/day.** Use the lowest effective dose for the shortest duration consistent with treatment goals. Tablets may be taken with or without food. Follow prescriber's instructions.

SPECIAL POPULATIONS

Renal impairment: Not recommended in severe renal impairment; patients on haemodialysis should not exceed 7.5 mg/day. Use cautiously in older adults and patients with renal, cardiac or hepatic disease. **Juvenile rheumatoid arthritis:** Where approved, 7.5 mg once daily for patients weighing at least 60 kg; do not use in lighter children under that labeling.

BOXED WARNING — CARDIOVASCULAR RISK

NSAIDs increase the risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which may be fatal. Risk may occur early and increase with duration. Meloxicam is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

BOXED WARNING — GASTROINTESTINAL RISK

NSAIDs increase the risk of serious gastrointestinal bleeding, ulceration and perforation, potentially fatal and sometimes occurring without warning. Risk is higher in older patients and those with a history of peptic ulcer or gastrointestinal bleeding.

CONTRAINDICATIONS

Hypersensitivity to meloxicam or any ingredient; history of asthma, urticaria or other allergic-type reactions after aspirin or other NSAIDs; use in the setting of CABG surgery. Assess other contraindications according to the locally approved product labeling.

WARNINGS AND PRECAUTIONS

Monitor for new or worsening hypertension, oedema, heart failure, kidney dysfunction, hyperkalaemia, liver injury, anaemia and serious skin reactions (including Stevens-Johnson syndrome). Stop treatment and seek urgent care for chest pain, sudden weakness, black stools, vomiting blood, breathing difficulty, severe rash or facial swelling.

RENAL AND HEPATIC SAFETY

NSAIDs can reduce renal blood flow and precipitate acute kidney injury, especially with dehydration, advanced age, renal disease, heart failure, diuretics or ACE inhibitors/ARBs. Monitor renal function where appropriate. Stop treatment if clinically significant liver injury is suspected.

DRUG INTERACTIONS

Anticoagulants, antiplatelets, aspirin, corticosteroids and SSRIs/SNRIs may increase bleeding risk. Avoid concurrent use with other NSAIDs. ACE inhibitors, ARBs and diuretics may increase renal risk or have reduced antihypertensive effect. Monitor lithium, methotrexate and cyclosporine/tacrolimus interactions.

PREGNANCY AND LACTATION

Avoid NSAIDs at about 30 weeks of pregnancy and later because of risk of premature closure of the fetal ductus arteriosus. From about 20 weeks, NSAIDs may cause fetal kidney dysfunction and oligohydramnios; if necessary, use the lowest dose for the shortest time under medical supervision. Breastfeeding decisions require individual assessment.

ADVERSE REACTIONS

Common reactions include dyspepsia, nausea, abdominal pain, diarrhoea, headache, dizziness and oedema. Serious reactions include gastrointestinal bleeding, heart attack, stroke, acute kidney injury, severe skin reactions, anaphylaxis and liver injury.

OVERDOSAGE

May cause nausea, vomiting, abdominal pain, drowsiness and gastrointestinal bleeding; severe overdose can cause renal failure, seizures or cardiovascular collapse. Seek urgent medical attention. Treatment is supportive; no specific antidote.

STORAGE

Store according to the approved Vcam product label, protected from moisture and excessive heat. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Vcam Tablets 7.5 mg: pack of 10 tablets.
Vcam Tablets 15 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.