BIXO CAPSULES

(Celecoxib 100 mg / 200 mg)
SELECTIVE COX-2 INHIBITOR / NSAID

DESCRIPTION

Bixo Capsules contain celecoxib, an oral non-steroidal anti-inflammatory drug (NSAID) that selectively inhibits cyclo-oxygenase-2 (COX-2). Celecoxib provides analgesic, anti-inflammatory and antipyretic effects.

COMPOSITION

Each **Bixo 100 mg Capsule** contains celecoxib 100 mg. Each **Bixo 200 mg Capsule** contains celecoxib 200 mg. Excipients according to the approved formula. For oral use.

CLINICAL PHARMACOLOGY

Celecoxib inhibits prostaglandin synthesis mainly through inhibition of COX-2, reducing pain and inflammation. It is absorbed following oral administration, extensively protein bound, metabolized principally by hepatic CYP2C9 and eliminated mostly as metabolites in feces and urine.

INDICATIONS

Celecoxib is indicated for relief of signs and symptoms of **osteoarthritis, rheumatoid arthritis and ankylosing spondylitis**; for the **management of acute pain** in adults; and for **primary dysmenorrhea**. Some prescribing information also includes juvenile rheumatoid arthritis in children aged 2 years and older; the suitability of available capsule strengths and local authorization must be considered.

DOSAGE AND ADMINISTRATION

Use the **lowest effective dose for the shortest duration** consistent with the treatment goal. Capsules may be taken with or without food. Dosage should be individualized by the prescriber.

Osteoarthritis: 200 mg once daily or 100 mg twice daily.

Rheumatoid arthritis: 100-200 mg twice daily.

Ankylosing spondylitis: 200 mg daily as one dose or two divided doses. If there is no benefit after six weeks, a physician may consider 400 mg daily; reassess if response remains inadequate.

Acute pain / primary dysmenorrhea: 400 mg initially, followed by an additional 200 mg on day 1 if needed. Thereafter, 200 mg twice daily as needed, under medical supervision.

Children: For juvenile rheumatoid arthritis (age 2 years or older), weight-based dosing may include 50 mg twice daily for 10-25 kg and 100 mg twice daily for more than 25 kg. **Bixo does not include a 50 mg strength;** do not attempt to achieve this dose with an intact 100/200 mg capsule without an approved method and physician direction.

Special populations: Reduce the dose by 50% for moderate hepatic impairment or known/suspected CYP2C9 poor metabolizers. Use in severe hepatic or renal impairment is not recommended.

CONTRAINDICATIONS

Hypersensitivity to celecoxib, sulfonamides or formulation components; history of asthma, urticaria or other allergic-type reactions after aspirin or other NSAIDs; use in the setting of coronary artery bypass graft (CABG) surgery. Do not use in patients with active severe allergic reactions to the product.

IMPORTANT WARNINGS

Serious cardiovascular events: NSAIDs may increase risk of myocardial infarction and stroke, which can be fatal. Risk may occur early in treatment and rise with dose or duration. Avoid immediately before or after CABG surgery.

Serious gastrointestinal events: Bleeding, ulceration and perforation of stomach or intestines may occur without warning and may be fatal. Elderly patients and those with previous ulcers or GI bleeding are at higher risk.

PRECAUTIONS

Assess cardiovascular and gastrointestinal risk before use. Monitor blood pressure, edema, renal function and signs of GI bleeding, particularly during longer treatment. Celecoxib may worsen hypertension or heart failure and cause renal injury or elevated potassium. Use with caution in dehydrated patients and in those with kidney or liver disease.

Discontinue if signs of serious rash, blistering, mucosal lesions, anaphylaxis, breathing difficulty or drug reaction with eosinophilia and systemic symptoms (DRESS) occur. Monitor for hepatotoxicity (jaundice, dark urine), anemia, and abnormal bleeding. Celecoxib may conceal signs of infection.

DRUG INTERACTIONS

Concomitant aspirin, other NSAIDs, anticoagulants (including warfarin), antiplatelet agents, oral corticosteroids or SSRIs/SNRIs can raise bleeding risk. ACE inhibitors, ARBs and diuretics may have reduced effects or increase renal risk. Celecoxib may increase lithium concentration; monitor if co-prescribed. Fluconazole (CYP2C9 inhibitor) can increase celecoxib exposure; monitor or adjust treatment. Review concomitant medicines with a healthcare professional.

PREGNANCY

Avoid NSAIDs from about **20 weeks of pregnancy** unless specifically directed because of risk of fetal renal dysfunction and oligohydramnios. Avoid from about **30 weeks onward** because of risk of premature closure of the fetal ductus arteriosus. Use earlier in pregnancy only after medical assessment. NSAIDs may reversibly impair ovulation.

LACTATION

Celecoxib is present in breast milk at low levels. The benefits of breastfeeding and need for treatment should be weighed against possible effects on the infant by the prescriber.

PEDIATRIC AND GERIATRIC USE

Pediatric dosing is indication- and weight-dependent. Safety of the 100/200 mg formulations in individual children must be assessed. Older patients are at greater risk of gastrointestinal bleeding and renal or cardiovascular complications; prescribe conservatively.

ADVERSE REACTIONS

Gastrointestinal: Dyspepsia, abdominal pain, nausea, diarrhea, flatulence, vomiting; less commonly ulceration, bleeding and perforation.

Nervous / general: Headache, dizziness, insomnia, fatigue, peripheral edema and respiratory tract symptoms.

Cardiovascular / renal: Hypertension, fluid retention, renal impairment, hyperkalemia and serious thrombotic events.

Skin / allergy: Rash, itching, urticaria, anaphylaxis, serious skin reactions including Stevens-Johnson syndrome and DRESS.

Other: Elevated liver enzymes, hepatitis, anemia and other blood abnormalities. Urgently assess chest pain, breathlessness, black stools, vomiting blood, jaundice or widespread rash.

OVERDOSAGE

Possible effects include lethargy, drowsiness, nausea, vomiting, epigastric pain, gastrointestinal bleeding, hypertension, renal failure or respiratory depression. There is no specific antidote. Obtain urgent medical care; management is supportive, with monitoring according to clinical status.

EFFECTS ON DRIVING AND MACHINERY

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

STORAGE CONDITIONS

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

PRESENTATION

Bixo Capsules 100 mg: Pack of 10 capsules.
Bixo Capsules 200 mg: Pack of 10 capsules.

Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.
30 Km, Multan Road, Lahore - Pakistan.

Prescription medicine.