ARCOXIA® (etoricoxib)

ONCE DAILY DOSE, ARCOXIA MAY BE TAKEN WITH OR WITHOUT FOOD[1]



Dosages[1]

- 120 mg/day
- 90 mg/day
- 60 mg/day
- 30 mg/day

Osteoarthritis			60 mg/day	30 mg/day
Chronic musculo-skeletal pain, Chronic low back pain			60 mg/day	
Rheumatoid arthritis		90 mg/day	60 mg/day	
Ankylosing spondylitis		90 mg/day	60 mg/day	
Acute pain	120 mg/day	90 mg/day		
Acute gouty arthritis	120 mg/day			
Post-operative acute dental surgery pain		90 mg/day		
Primary dysmenorrhea	120 mg/day			
Post-operative acute gynecological surgery pain	120 mg/day	90 mg/day		

Reference: 1. Arcoxia Product Circular. (Feb 2023)

ARCOXIA (etoricoxib) is a member of a class of arthritis/analgesia medications called Coxibs. ARCOXIA is a highly selective inhibitor of cyclooxygenase-2 (COX-2). **INDICATIONS:** - Acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA) - Treatment of ankylosing spondylitis (AS) - Treatment of acute gouty arthritis - Relief of chronic musculo-skeletal pain, including chronic low back pain - Relief of acute pain including dental surgery - Treatment of primary dysmenorrhea - Treatment of moderate to severe acute post-operative pain associated with abdominal gynecological surgery. **DOSAGE AND ADMINISTRATION: Osteoarthritis:** The recommended dose is 30 mg or 60 mg once daily. Rheumatoid Arthritis: The recommended dose is 60 mg or 90 mg once daily. The minimum effective daily dose is 60 mg once daily. In some patients, 90 mg once daily may provide increased therapeutic benefit. Ankylosing Spondylitis: The recommended dose is 60 mg or 90 mg once daily. Chronic musculo-skeletal pain, including chronic low back pain: The recommended dose is 60 mg once daily. Acute Pain: For acute pain conditions, the recommended dose is 90 mg or 120 mg once daily. ARCOXIA should be used only for the acute symptomatic period limited to a maximum of 8 days -Acute Gouty Arthritis: The recommended dose is 120 mg once daily. - Primary Dysmenorrhea: The recommended dose is 120 mg once daily. - Post-operative Dental Pain: The recommended dose is 90 mg once daily. - Post-operative Gynecological Pain: The recommended dose is 90 mg once daily and can be increased to a maximum 120 mg once daily. *Hepatic Insufficiency* In patients with mild hepatic insufficiency (Child-Pugh score 5-6), a dose of 60 mg once daily should not be exceeded. In patients with moderate hepatic insufficiency (Child-Pugh score 7-9), the dose should be reduced; a dose of 60 mg every other day should not be exceeded, administration of 30 mg once daily can also be considered. There are no clinical or pharmacokinetic data in patients with severe hepatic insufficiency (Child-Pugh score >9). *Renal Insufficiency* In patients with advanced renal disease (creatinine clearance <30 ml/min), treatment with ARCOXIA is not recommended. No dosage adjustment is necessary for patients with lesser degrees of renal insufficiency (creatinine clearance: 30 mL/min). **CONTRAINDICATIONS:** - patients with known hypersensitivity to any component of this product- patients with active peptic ulceration or gastro-intestinal (GI) bleeding - patients with severe hepatic dysfunction (Child-Pugh score >9)- patients with estimated creatinine clearance <30 mL/min - patients who have developed signs of asthma, acute rhinitis, nasal polyps, angioneurotic oedema or urticaria following the administration of aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs) - pregnancy and lactation - children under 16 years of age - patients with inflammatory bowel disease - patients with congestive heart failure (NYHA II-IV)- patients with hypertension whose blood pressure has not been adequately controlled - patients with established ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease (including patients who have recently undergone coronary artery bypass graft surgery or angioplasty). **WARNING AND PRECAUTIONS:** - Contraindicate in patients with known hypersensitivity to any component of this product, pregnancy and lactation. - Contraindicate in patients who have recently undergone coronary artery bypass graft surgery. - Contraindicate in patients with cardiovascular or cerebrovascular disease. - Contraindicate in patients with un-controlled hypertension. - Contraindicate in patients with myocardial infarction or congestive heart failure NYHA II-IV. - Contraindicate in patients with history of ischemic heart disease or history of paralysis from cerebrovascular disease. - Caution should be used in patients with risk factors for cardiovascular events e.g, hypertension, hyperlipidaemia, diabetes mellitus, smoking, elderly. - Caution should be used in patients with liver or renal disease. There is a further increase in the risk of gastrointestinal adverse effects (gastrointestinal ulceration or other gastrointestinal complications) for etoricoxib when taken concomitantly with acetylsalicylic acid (even at low doses). Use with caution when initiating treatment with ARCOXIA in patients with considerable dehydration. It is advisable to rehydrate patients prior to starting therapy with ARCOXIA. ARCOXIA should be used with caution in patients who have previously experienced acute asthmatic attacks, urticaria, or rhinitis, which were precipitated by salicylates or non-selective cyclooxygenase inhibitors. Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs and some selective COX-2 inhibitors during post-marketing surveillance. Etoricoxib should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. ARCOXIA may mask fever, which is a sign of infection. The physician should be aware of this when using ARCOXIA in patients being treated for infection. **Use in pregnancy, lactation and pediatric:** The use of ARCOXIA, as with any drug substance known to inhibit COX-2, is not recommended in women attempting to conceive. Etoricoxib is excreted in the milk of lactating rats. Women who use etoricoxib must not breast feed. Safety and effectiveness of etoricoxib in pediatric patients have not been established. **DRUG INTERACTIONS:** Standard monitoring of INR values should be conducted when therapy with ARCOXIA is initiated or changed, particularly in the first few days, in patients receiving warfarin or similar agents. This interaction should be considered when ARCOXIA is co-administered with rifampin. Monitoring for methotrexate-related toxicity should be considered when ARCOXIA at doses greater than 90 mg daily and methotrexate are administered concomitantly. The interaction should be given consideration in patients taking ARCOXIA concomitantly with Angiotensin Converting Enzyme (ACE) Inhibitors and Angiotensin II Antagonists (AIIAs). Lithium. Concomitant administration of etoricoxib with doses of aspirin above those for cardiovascular prophylaxis or with other NSAIDs is not recommended. Renal function should be monitored when etoricoxib and either of cyclosporin or tacrolimus are used in combination. Increase in EE concentration should be considered when selecting an oral contraceptive for use with etoricoxib. An increase in EE exposure can increase the incidence of adverse events associated with oral contraceptives. Increases in estrogenic concentration should be taken into consideration when selecting post-menopausal hormone therapy for use with ARCOXIA because the increase in oestrogen exposure might increase the risk of adverse events associated with HRT. Patients at high risk of digoxin toxicity should be monitored when etoricoxib and digoxin are administered concomitantly. It may be prudent to exercise care when administering etoricoxib concurrently with other drugs primarily metabolised by human sulfotransferases (e.g. oral salbutamol and minoxidil). **SIDE EFFECTS:** In clinical trials. These common adverse experiences occurred in ≥1% and <10% of patients treated with ARCOXIA and at an incidence greater than placebo: asthenia/fatigue, dizziness, oedema/fluid retention, lower extremity edema, flu-like disease, hypertension, abdominal pain, flatulence, diarrhea, dyspepsia, heartburn, epigastric discomfort, nausea, headache, ALT increased, AST increased. In the MEDAL Study, The incidence of discontinuations for hypertension-related adverse events was less than 3% in each treatment group; ARCOXIA 60 and 90 mg demonstrated significantly higher rates of discontinuations for these events than diclofenac. The incidence of discontinuations due to atrial fibrillation was higher for etoricoxib compared to diclofenac. **Post-marketing experience:** thrombocytopenia, gastroenteritis, upper respiratory infection, urinary tract infection, hypersensitivity reactions, including angioedema, anaphylactic/ anaphylactoid reactions including shock, appetite increase or decrease, weight gain, hyperkalemia, anxiety, depression, mental acuity decreased, confusion, hallucinations, restlessness, dysgeusia, insomnia, paresthaesia/hypaesthesia, somnolence, blurred vision, tinnitus, congestive heart failure, non-specific ECG changes, myocardial infarction, palpitations, angina, arrhythmia, flushing, cerebrovascular accident, hypertensive crisis, cough, dyspnoea, epistaxis, bronchospasm, pulmonary embolism, abdominal distention, acid reflux, bowel movement pattern change, constipation, dry mouth, gastroduodenal ulcer, irritable bowel syndrome, oesophagitis, oral ulcers, peptic ulcers including perforation and bleeding (mainly in elderly patients), vomiting, gastritis, hepatitis, jaundice, hepatic failure, ecchymosis, facial oedema, pruritus, erythema, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria, fixed drug eruption, muscular cramp/spasm, musculoskeletal pain/stiffness, proteinuria, renal insufficiency, including renal failure, chest pain, blood urea nitrogen increased, creatine phosphokinase increased, haematocrit decreased, haemoglobin decreased, hyperkalaemia, leukocytes decreased, platelets decreased, serum creatinine increased, uric acid increased. The following serious undesirable effects have been reported in association with the use of NSAIDs and cannot be ruled out for etoricoxib: nephrotoxicity including interstitial nephritis and nephrotic syndrome; hepatotoxicity, including hepatic failure. **STORAGE CONDITION:** Store below 30°C.

ความถูกต้องของโฆษณานี้ เป็นความรับผิดชอบของผู้โฆษณา
มิได้ดำเนินการโดยสำนักงานคณะกรรมการอาหารและยา

โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา
Arcoxia Reg.No: 30 mg 1C 115/55(N); 60 mg 1C 116/55(N);
90 mg 1C 117/55(N); 120 mg 1C 118/55(N)
ใบอนุญาตโฆษณาเลขที่ ฆศ.2-207/2569
TH-ARC-022026-002
TH-CXB-110342

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