IDENTIFYING THE ELYXYB PATIENT

Elyxyb® (celecoxib) Oral Solution | THINK FAST

Make ELYXYB the first choice for your patients with rapid onset migraine or morning migraine when triptans are not enough

Find the ELYXYB patient in your practice:

PATIENT TYPE:

- Patient has insufficient response on one or two triptans
- Needs rapid pain freedom to get back to work, school, and/or family responsibilities

Clinical Presentation:

- ☐ Rapid onset migraine–comes on suddenly without warning
- ☐ Morning migraine is present the moment the patient wakes up

Medication History:

- ☐ Patient was on an OTC NSAID at some point
- ☐ One or two triptans were not enough
- ☐ Patient is not a good candidate for gepants because they are not fast enough

When patients need an option that works FAST, go to ELYXYB

INDICATION

ELYXYB® (celecoxib) oral solution is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use
ELYXYB is not indicated for the preventive treatment of migraine.

Explore the fast, lasting effect of ELYXYB

IMPORTANT SAFETY INFORMATION about ELYXYB®

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.**
- **ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.**

Gastrointestinal Bleeding, Ulceration, and Perforation

- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events.**

Please see Important Safety Information continued on the next page and full Prescribing Information, including Boxed Warning.

IMPORTANT SAFETY INFORMATION about ELYXYB® (cont'd)

CONTRAINDICATIONS

ELYXYB is contraindicated in the following patients:

- Known hypersensitivity to celecoxib or any components of the drug product or sulfonamides.
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS AND PRECAUTIONS

Post-MI Patients: Avoid the use of ELYXYB in patients with a recent MI unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

Hepatotoxicity: Elevations of ALT or AST have been reported in patients with NSAIDs. In addition, rare, sometimes fatal, cases of severe hepatic injury, including fulminant hepatitis, liver necrosis, and hepatic failure, have been reported. Inform patients of warning signs and symptoms of hepatotoxicity. Discontinue if abnormal liver tests persist or worsen or if clinical signs and symptoms of liver disease develop.

Hypertension: NSAIDs, including ELYXYB, can lead to new onset of hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking some antihypertension medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.

Heart Failure and Edema: Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Renal Toxicity: Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury and may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of ELYXYB in patients with severe renal impairment unless benefits are expected to outweigh the risk of worsening renal function. If ELYXYB is used in patients with advanced renal disease, monitor patients for signs of worsening renal function.

Hyperkalemia: Increases in serum potassium concentration, including hyperkalemia, have been reported with use of NSAIDs, even in some patients without renal impairment. In patients with normal renal function, these effects have been attributed to a hyporeninemic-hypoaldosteronism state.

Anaphylactic Reactions: Celecoxib has been associated with anaphylactic reactions in patients with and without known hypersensitivity to celecoxib and in patients with aspirin-sensitive asthma. Celecoxib is a sulfonamide and both NSAIDs and sulfonamides may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.

Exacerbation of Asthma Related to Aspirin Sensitivity: ELYXYB is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without known aspirin sensitivity).

Serious Skin Reactions: Serious skin reactions have occurred following treatment with celecoxib, including erythema multiforme, exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP). These serious events may occur without warning and can be fatal. Discontinue ELYXYB at the first appearance of skin rash or any other sign of hypersensitivity.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): DRESS has been reported in patients taking NSAIDs. Some of these events have been fatal or life-threatening. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy, and/or facial swelling. Eosinophilia is often present. If such signs or symptoms are present, discontinue ELYXYB and evaluate the patient immediately.

Medication Overuse Headache: Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, NSAIDs, or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication overuse headache). Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms may be necessary.

Premature Closure of Fetal Ductus Arteriosus: ELYXYB may cause premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs, including ELYXYB, in pregnant women starting at about 30 weeks gestation and later.

Oligohydramnios/Neonatal Renal Impairment: Use of NSAIDs, including ELYXYB, at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. If NSAID treatment is necessary between about 20 weeks and 30 weeks gestation, limit ELYXYB use to the lowest effective dose and shortest duration possible. Discontinue ELYXYB if oligohydramnios occurs.

Hematological Toxicity: Anemia has occurred in NSAID-treated patients. Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia or blood loss. NSAIDs, including ELYXYB, may increase the risk of bleeding events. Monitor patients for signs of bleeding. Masking of Inflammation and Fever: The pharmacological activity of celecoxib in reducing inflammation, and possibly fever, may diminish the utility of diagnostic signs in detecting infections.

Laboratory Monitoring: Because serious GI bleeding, hepatotoxicity, and renal injury can occur without warning symptoms or signs, consider monitoring patients on long-term NSAID, including ELYXYB, treatment with a CBC and a chemistry profile periodically.

Disseminated Intravascular Coagulation (DIC): ELYXYB is not indicated in pediatric patients or for the treatment of juvenile rheumatoid arthritis (JRA). Disseminated intravascular coagulation has occurred with use of celecoxib capsules in pediatric patients with systemic-onset JRA, which required monitoring for signs and symptoms of abnormal clotting or bleeding.

DRUG INTERACTIONS

Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, SSRIs/SNRIs): Monitor patients for bleeding who are concomitantly taking ELYXYB with drugs that interfere with hemostasis. Concomitant use of ELYXYB and oral corticosteroids, antiplatelet drugs (e.g., aspirin), anticoagulants, or selective serotonin reuptake inhibitors (SSRIs), is not recommended. ACE Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with ELYXYB may diminish the antihypertensive effect of these drugs. Monitor blood pressure.

ACE Inhibitors and ARBs: Concomitant use with ELYXYB in the elderly, volume-depleted, or those with renal impairment may result in deterioration of renal function. In such high-risk patients, monitor for signs of worsening renal function.

Diuretics: NSAIDs can reduce natriuretic effect of furosemide and thiazide diuretics. Monitor patients to assure diuretic efficacy including antihypertensive effects.

Digoxin: Concomitant use with ELYXYB can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels.

USE IN SPECIFIC POPULATIONS

Pregnancy: Use of NSAIDs during the third trimester of pregnancy increases the risk of premature closure of the fetal ductus arteriosus. Avoid use of NSAIDs in pregnant women starting at 30 weeks gestation.

Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of ELYXYB in women who have difficulties conceiving.

ADVERSE REACTIONS

Most common adverse reaction (at least 3% and greater than placebo) reported by patients treated with ELYXYB in the clinical trials was dysgeusia.

Please see full Prescribing Information, including Boxed Warning.

To report SUSPECTED ADVERSE REACTIONS, contact Scilex Holding Company at 1-866-SCILEX3 or FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch.

Intended for healthcare professionals of the United States of America only.