ELYXYB PHARMACIST FACT SHEET

Elyxyb®
(celecoxib)
Oral Solution

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.

IMPORTANT SAFETY INFORMATION about ELYXYB®

WARNING: RISK OF SERIOUS CARDIOVASCULAR and GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

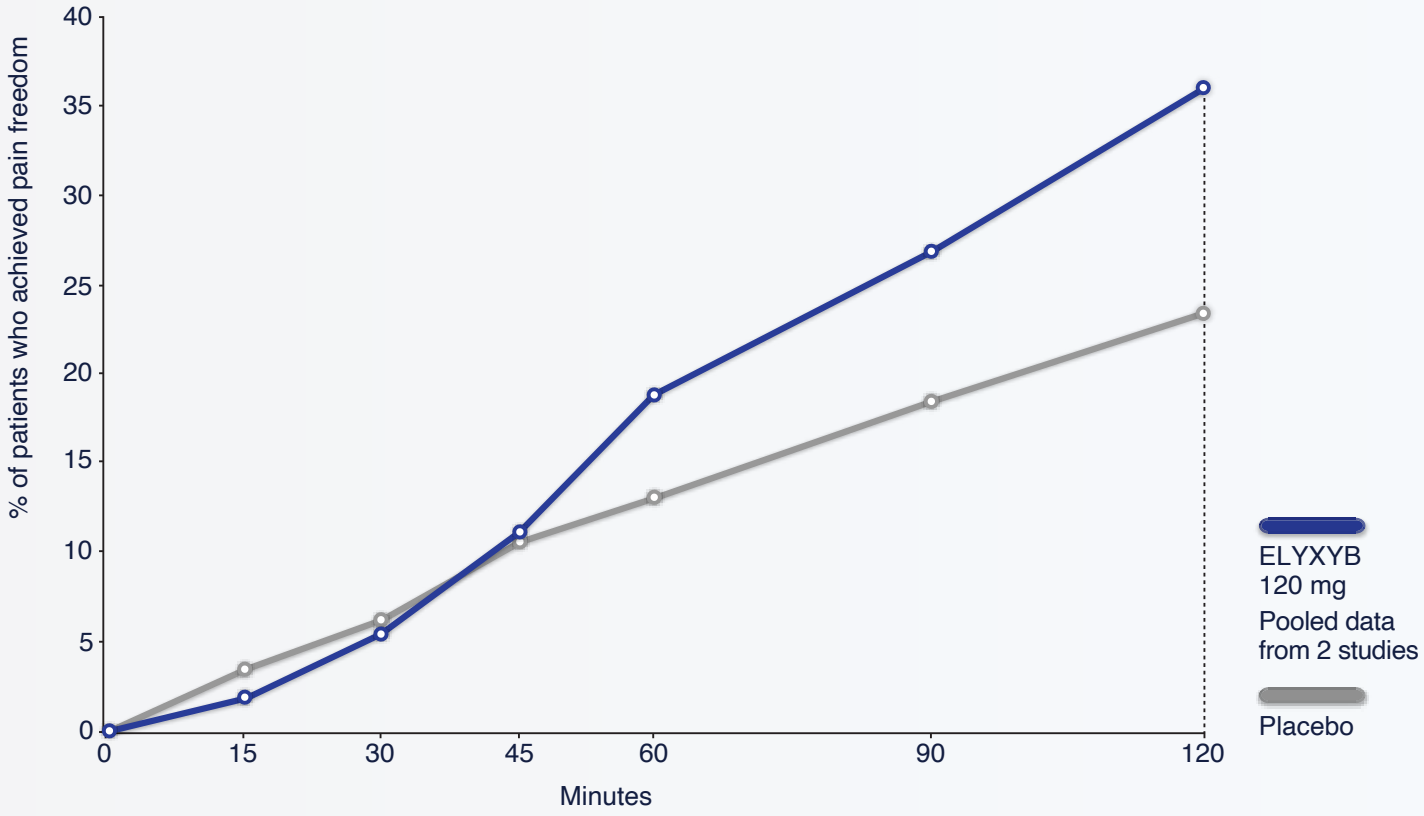
- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.**
- **ELYXYB is contraindicated in the 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 on the following pages and full Prescribing Information, including Boxed Warning.

Patients on ELYXYB® (celecoxib) oral solution achieved significant pain freedom in just 60 minutes vs placebo[1-3]*



PATIENTS ON ELYXYB ACHIEVED SIGNIFICANT, LASTING RELIEF[1,4,5]

34% **PAIN FREEDOM**
*vs 24% on placebo[3]**
P=0.0002

57% **MBS FREEDOM**
*vs 44% on placebo[3]**
P<0.0001

92% **NO RECURRENCE**
for patients who had pain freedom at 2 hours[4]

Phase 3 trial designs: 1253 patients were enrolled across 2 identical, multicenter, randomized, double-blind trials. Patients were screened and then randomized 1:1 to receive either ELYXYB oral solution (120 mg) or placebo (administered within 1 hour of onset of a moderate-to-severe migraine attack in treatment period 1). The coprimary endpoints were pain freedom and MBS freedom at 2 hours.[1,6,7]

*Pooled data from study 1 and study 2.[4]

MBS=most bothersome symptom.

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.

Please see Important Safety Information on the following pages and full Prescribing Information, including Boxed Warning.

Extinguish migraine pain fast with a novel formulation[1,8,9]

Actual size.

EASY FOR PATIENTS TO USE[1]

- QD Once-daily dosing
- Ready-to-drink bottles
- Taken with or without food
- Stored at room temperature

- The recommended and maximum daily dose is 120 mg (4.8 mL) taken orally[1]
- For patients with moderate hepatic impairment (Child-Pugh Class B), the recommended and maximum daily dose is 60 mg (2.4 mL)[1]
- After opening a bottle of ELYXYB, any unused portion should be discarded immediately[1]

IMPORTANT SAFETY INFORMATION ABOUT ELYXYB® (cont'd)

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.

Please see Important Safety Information on the following pages and full Prescribing Information, including Boxed Warning.

Order ELYXYB

ORDERING INFORMATION[1]

NDC number	69557-333-01
How supplied	ELYXYB (celecoxib) Oral Solution, 120 mg/4.8 mL (25 mg/mL) is a clear colorless oral solution supplied with a child resistant cap. Each carton contains six (6) glass bottles, a Full Prescribing Information, Medication Guide, and Instructions for Use.
Order minimum	No limit.

- Not AB-rated/interchangeable with generic celecoxib formulations

See how patients can get started with ELYXYB for free

Elyxyb®
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Fast migraine relief is free with the ELYXYB copay card![1,6*]

Eligible commercially insured patients pay as little as $0 on their first prescription (6 doses) of ELYXYB and only $25 on each monthly refill.*

Help your patients access ELYXYB:

- Initiate prior authorization so patients can access their prescription
- Give them an ELYXYB patient brochure, which includes a copay card

Patient Access Support & Savings Program

Elyxyb® (celecoxib) Oral Solution Passport

BIN# 600426
PCN# 54
GRP# EC45401001
ID# 39854504969

Pay as little as **$0** on each prescription and $0 for refills*

*Commercial insurance patients only. Terms and conditions apply.

*Eligible patients will pay $0 on their first fill and $25 for their subsequent fills of ELYXYB (celecoxib) Oral Solution. Offer valid for up to 12 uses. A valid Prescriber ID# is required on the prescription.
Patient Instructions: In order to redeem this offer you must have a valid prescription for ELYXYB. Follow the dosage instructions given by the doctor. This offer may not be redeemed for cash. By using this offer, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described in the Restrictions section below. Patients with questions about the ELYXYB Savings offer should call (1-844-414-2225).
Pharmacist: When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. By participating in this program, you are certifying that you will comply with the terms and conditions described in the Restrictions section below.
Pharmacist Instructions for a Patient With an Eligible Third Party: Submit the claim to the primary Third Party Payer first, then submit the balance due to Change Healthcare as a Secondary Payer COB (coordination of benefits) with patient responsibility amount and a valid Other Coverage Code (eg, 8). The patient is responsible for $0 on first fill and the first $25 on subsequent fills and reimbursement will be received from Change Healthcare. Valid Other Coverage Code required. For any questions regarding Change Healthcare online processing, please call the Help Desk at (1-800-433-4893).
Restrictions: This offer is valid in the United States. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare, or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payor of the existence and/or value of this offer. It is illegal to (or offer to) sell, purchase, or trade this offer. Program expires 12/31/24. This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Program
managed by ConnectiveRx on behalf of SCILEX Pharmaceuticals. The parties reserve the right to rescind, revoke, or amend this offer without notice at any time.

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WHEN TRIPTANS AREN'T ENOUGH,[10]

START ELYXYB FOR FAST PAIN FREEDOM WITHOUT HEADACHE RECURRENCE[1,2,4,5,10]

IMPORTANT SAFETY INFORMATION ABOUT ELYXYB® (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

References: 1. ELYXYB [Prescribing Information]. Palo Alto, CA: Scilex Pharmaceuticals, Inc.; Sep 2021. **2.** Tepper SJ, et al. Poster presented at: 2023 Annual Brain Week Conference. September 6-8, 2023; Las Vegas, NV. **3.** Tepper SJ, et al. Poster presented at: American Headache Society 64th Annual Meeting. June 9-12, 2022; Denver, CO. **4.** Data on file. DFN-15-CD-006. **5.** Data on file. DFN-15-CD-007. **6.** Lipton RB, et al. *J Pain Res*. 2021;14:549-560. **7.** Lipton RB, et al. *J Pain Res*. 2021;14:2529-2542. **8.** Pal A, et al. *Clin Drug Investig*. 2017;37(10):937-946. **9.** Ailani J, et al. *Pain Ther*. 2023;12(3):655-669. **10.** Ruscheweyh R, et al. *J Headache Pain*. 2023;24(1):135.

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SCILEX PHARMACEUTICALS