VYSCOXA™
(celecoxib)
ORAL SUSPENSION

A SOLUTION FOR OA, RA, AS, and JRA MANAGEMENT

IMPORTANT SAFETY INFORMATION ABOUT VYSCOXA™

INDICATIONS AND USAGE

VYSCOXA is indicated:

- In adults for the management of the signs and symptoms of: Osteoarthritis (OA), Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS).
- In pediatric patients two years of age and older for the management of the signs and symptoms of: Juvenile Rheumatoid Arthritis (JRA).

Limitation of Use

- VYSCOXA must be administered on an empty stomach at least 2 hours before or 1 hour after food. Taking VYSCOXA with food results in plasma exposures of celecoxib up to 50% higher than intended. If patients cannot tolerate VYSCOXA in the fasted state, discontinue use of VYSCOXA.
- VYSCOXA is **NOT** indicated for the management of acute pain or treatment of primary dysmenorrhea.

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.
- VYSCOXA 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 additional Important Safety Information throughout this brochure and included Full Prescribing Information before prescribing VYSCOXA™

carwin PHARMACEUTICAL ASSOCIATES

INDICATIONS AND USAGE

VYSCOXA™ (celecoxib) oral suspension is indicated for the management of the signs and symptoms of:[1]

ADULTS:

Osteoarthritis (OA)

Rheumatoid Arthritis (RA)

Ankylosing Spondylitis (AS)

PEDIATRIC PATIENTS:
2 years of age and older

Juvenile Rheumatoid Arthritis (JRA)

DOSAGE AND ADMINISTRATION

- Carefully consider the potential benefits and risks of VYSCOXA and other treatment options before deciding to use VYSCOXA. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
- **The maximum single dose of VYSCOXA is 200 mg (20 mL).** Administering more than 200 mg (20 mL) in a single dose of the VYXCOXA suspension may result in higher than intended plasma concentrations of celecoxib. In patients requiring a single dose greater than 200 mg (20 mL), use a different product.
- VYSCOXA must be taken on an empty stomach at least 2 hours before or 1 hour after food.
- For patients who cannot tolerate dosing with VYSCOXA on an empty stomach, discontinue the use of this product. Do not advise the patient to take VYSCOXA with food.

OSTEOARTHRITIS (OA):	200 mg (20 mL) once daily or 100 mg (10 mL) twice daily
RHEUMATOID ARTHRITIS (RA):	100 mg (10 mL) to 200 mg (20 mL) twice daily
ANKYLOSING SPONDYLITIS (AS):	200 mg (20 mL) once daily single dose or 100 mg (10 mL) twice daily. If no effect is observed after 6 weeks, a trial of 200 mg (20 mL) twice daily may be of benefit
JUVENILE RHEUMATOID ARTHRITIS (JRA):	50 mg (5 mL) twice daily in patients 10 kg to 25 kg. 100 mg (10 mL) twice daily in patients more than 25 kg.

VYSCOXA™
(celecoxib)
ORAL SUSPENSION

VYSCOXA™
(celecoxib)
ORAL SUSPENSION

IMPORTANT SAFETY INFORMATION ABOUT VYSCOXA™ *(CONTINUED)*

CONTRAINDICATIONS
- 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 CABG surgery.

WARNINGS AND PRECAUTIONS
- Hepatotoxicity: 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: Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Monitor blood pressure.
- Heart Failure and Edema: Avoid use of VYSCOXA in patients with severe heart failure unless benefits are expected to outweigh risk of worsening heart failure.
- Renal Toxicity: Monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia. Avoid use of VYSCOXA in patients with advanced renal disease unless benefits are expected to outweigh risk of worsening renal function.

WARNINGS AND PRECAUTIONS (CONTINUED)
- Anaphylactic Reactions: Seek emergency help if an anaphylactic reaction occurs.
- Exacerbation of Asthma Related to Aspirin Sensitivity: VYSCOXA is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).
- Serious Skin Reactions: Discontinue VYSCOXA at first appearance of skin rash or other signs of hypersensitivity.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue and evaluate clinically.
- Fetal Toxicity: Limit use of NSAIDs, including VYSCOXA, between about 20 to 30 weeks in pregnancy due to the risk of oligohydramnios/fetal renal dysfunction. Avoid use of NSAIDs in women at about 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/fetal renal dysfunction and premature closure of the fetal ductus arteriosus.
- Hematologic Toxicity: Monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

ADVERSE REACTIONS
Most common adverse reactions in arthritis trials (>2% and >placebo) are: abdominal pain, diarrhea, dyspepsia, flatulence, peripheral edema, accidental injury, dizziness, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, rash.

To report SUSPECTED ADVERSE REACTIONS, contact Carwin Pharmaceutical Associates, LLC at 1-844-700-5011 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS
- Drugs that Interfere with Hemostasis (e.g., warfarin, aspirin, selective serotonin reuptake inhibitors (SSRIs)/ serotonin norepinephrine reuptake inhibitors (SNRIs)): Monitor patients for bleeding who are concomitantly taking VYSCOXA with drugs that interfere with hemostasis. Concomitant use of VYSCOXA and analgesic doses of aspirin is not generally recommended.

IMPORTANT SAFETY INFORMATION ABOUT VYSCOXA™ *(CONTINUED)*

DRUG INTERACTIONS (CONTINUED)
- Angiotensin Converting Enzyme (ACE) Inhibitors, Angiotensin Receptor Blockers (ARB), or Beta-Blockers: Concomitant use with VYSCOXA may diminish the antihypertensive effect of these drugs. Monitor blood pressure.
- ACE Inhibitors and ARBs: Concomitant use with VYSCOXA in 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 VYSCOXA can increase serum concentration and prolong half-life of digoxin. Monitor serum digoxin levels.

USE IN SPECIFIC POPULATIONS
Infertility: NSAIDs are associated with reversible infertility. Consider withdrawal of VYSCOXA in women who have difficulties conceiving.

Please see additional Important Safety Information, including Boxed Warning throughout this brochure and included Full Prescribing Information before prescribing VYSCOXA™

Please see additional Important Safety Information, including Boxed Warning throughout this brochure and included Full Prescribing Information before prescribing VYSCOXA™

A SOLUTION YOU CAN TRUST

VYSCOXA™ (CELECOXIB) IS EQUIVALENT TO CELEBREX® BASED ON OVERALL SYSTEMIC EXPOSURE:[1]

- The overall systemic exposure (AUC) of a 200 mg dose of VYSCOXA was equivalent to celecoxib capsules with a decrease in peak plasma levels (i.e., C_{max}) of 22%.

CELEBREX® is a registered trademark of Viatris Holdings LLC

VYSCOXA™ BENEFITS YOUR PATIENTS:[1]

- 10 mg/mL Oral Suspension for patients with difficulty swallowing solid medication.
- Sugar-free and dye-free. Flavorless, but with a sweet, palatable taste.
- **OA:** Celecoxib is clinically proven to significantly reduce joint pain compared to sugar pill†
- **RA:** Celecoxib demonstrated significant reduction in joint tenderness/pain and joint swelling compared to sugar pill†

†*Effectiveness of celecoxib was shown to be similar to that of naproxen 500 mg twice daily.*

Most commercially insured patients Pay As Little As $0*

**Terms & Conditions apply.*

CELECOXIB HAS A FAVORABLE CARDIOVASCULAR AND GASTROINTESTINAL PROFILE VS OTHER NSAIDS:#

CELECOXIB PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCULAR DISEASE TAKING CELECOXIB 100-200 MG 2 TIMES A DAY

Did not show an increased risk of having a stroke, heart attack, or dying from a cardiovascular cause compared with patients taking ibuprofen 600-800 mg (3 times a day) or naproxen 375-500 mg (2 times a day)‡

In a substudy of 444 patients, celecoxib showed a decrease in mean blood pressure compared to patients taking ibuprofen 600-800 mg (3 times a day),‡ or patients taking naproxen 375-500 mg (2 times a day)§

‡*This is statistically significant.* §*Comparison not statistically significant.*

#*National Library of Medicine (U.S.). (2021, March 3 - 2025, December 30). A Randomized, Double Blind, Parallel-group Study Of Cardiovascular Safety In Osteoarthritis Or Rheumatoid Arthritis Patients With Or At High Risk For Cardiovascular Disease Comparing Celecoxib With Naproxen And Ibuprofen. Identifier NCT00346216. https://clinicaltrials.gov/study/NCT00346216*

VYSCOXA™ (celecoxib) ORAL SUSPENSION

IMPORTANT SAFETY INFORMATION ABOUT VYSCOXA™

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.
- VYSCOXA 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.

INDICATIONS AND USAGE

VYSCOXA is indicated:

- In adults for the management of the signs and symptoms of: Osteoarthritis (OA), Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS).
- In pediatric patients two years of age and older for the management of the signs and symptoms of: Juvenile Rheumatoid Arthritis (JRA).

Limitation of Use

- VYSCOXA must be administered on an empty stomach at least 2 hours before or 1 hour after food. Taking VYSCOXA with food results in plasma exposures of celecoxib up to 50% higher than intended. If patients cannot tolerate VYSCOXA in the fasted state, discontinue use of VYSCOXA.
- VYSCOXA is **NOT** indicated for the management of acute pain or treatment of primary dysmenorrhea.

Please see additional Important Safety Information throughout brochure and included Full Prescribing Information before prescribing VYSCOXA™

carwin PHARMACEUTICAL ASSOCIATES

REFERENCES: 1. VYSCOXA prescribing information. Carwin Pharmaceutical Associates, LLC, Hazlet, NJ; 2025

15370-VYS-01
Rev. 12/2025