

LIMBREL[®] Product Profile



Product Background

- **Usage** – For the safe clinical dietary management of the metabolic processes of osteoarthritis (OA).
- **Ingredients** – Primarily baicalin from *Scutellaria baicalensis*, catechin from *Acacia catechu*, and citrated zinc bisglycinate. Each capsule of LIMBREL contains 250 mg or 500 mg of flavocoxid and 50 mg of citrated zinc bisglycinate (10 mg elemental zinc). Capsules do not contain fructose, glucose, sucrose, lactose, gluten or flavors.
- **Administration** – Take 1 capsule twice daily with or without food, or as directed by a physician.
- **How Supplied** – Bottle of 60 capsules (30-day supply). Distributed by prescription only
- **FDA Regulated Product Class** – Medical Food (not a drug or dietary supplement).
- **Distribution** – Nationwide by prescription at retail pharmacies.

	LIMBREL250™ (68040-605-16)	LIMBREL500™ (68040-606-16)
Cardinal	4231163	4231171
McKesson	1252618	1252790
Amerisource Bergen	480-079	480-095

- **Promotion** – Only via education and detailing to medical professionals (MD/DO/PA/NP's).
- **Category** – Arthritis affects 1 in 3 Americans and is the #1 cause of disability. Arthritis costs the U.S. economy \$82.5 billion annually, including over \$6 billion in prescription product costs and growing at >10% annually with aging population. Many products have had considerable cardiovascular and gastrointestinal safety concerns.

Product Benefits

- **Effectiveness**
 - COX and LOX dual inhibition of AA metabolism – regulates metabolic activities on COX-1, COX-2 and 5-LOX via dietary management. Limbrel is not a selective COX-1 or COX-2 inhibitor.
 - Antioxidant activity – manages ROS-induced cartilage degradation and inflammation.
(COX = cyclooxygenase, LOX = lipoxygenase, AA = arachidonic acid, ROS = reactive oxygen species)
 - Demonstrated efficacy in clinical studies – in one study, Limbrel performed nearly identical to naproxen:

Double-blind, Randomized, Active Comparator Controlled Clinical Study of Knee OA

Measures	Limbrel 500 mg BID	Naproxen 500 mg BID	Within-group p-value	Between-group difference
Improvements in WOMAC (Joint discomfort, stiffness, mobility)	+32%	+36%	p≤0.001	Not different between groups statistically
% of Patients with improvements (Subject assessment of disease, and discomfort)	87%	88%	p≤0.001	

- **Safety**
 - Low toxicity in upper GI – expected due to modest inhibition of COX-1 and 5-LOX inhibition.
 - In clinical studies, side effects rates were only slightly higher than placebo.
 - Side effects rate = 0.1% in patients taking LIMBREL as reported in post marketing surveillance.
 - G.R.A.S. ingredients – Generally Recognized As Safe (G.R.A.S.) is the strict FDA safety standard applied to foods that are safe for public consumption.

Reimbursement Status

- **Limbrel Coverage** – Reimbursed by many national and regional plans on Tier-3 co-pay (mostly \$40-60 per prescription).
- **Cost Savings**
 - *Daily Product Cost:* Limbrel is on average 30% less expensive than leading branded Rx products for OA.
 - *Total Cost of Care:* Minimal side effects should significantly reduce costs otherwise due to serious adverse events.
 - *Rebates:* Attractive rebates to managed care organizations and buying groups are available.