

LIMBREL® Post-Marketing Surveillance (June 2011)

(Limbrel 500mg, 250mg, 500-50mg, 250-50mg and 525mg)



Limbrel500
(flavocoxid and citrated zinc bisglycinate) 500 mg/50 mg

The table below lists the side effects reported by patients and physicians in post-marketing surveillance, as reported from introduction in 2004 through June 2011. Reported cases of rash and itching may have been associated with allergies to Limbrel's flavonoid ingredients and were transient in nature. One of the reported cases of heart palpitation occurred in a patient with a history of heart palpitations. Hypersensitivity pneumonitis is a rare, but serious complication of Limbrel therapy. Thus far, with more than 294,000 people exposed to the product, 11 cases have been reported. These generally present with fever, dry cough, hypoxemia and diffuse sterile pulmonary infiltrates. All patients have required treatment with high dose corticosteroids and supplemental oxygen and all have recovered without residua. Of the reported cases of elevated liver tests most were mild and without symptoms. However, 6 cases were associated with clinical jaundice and higher elevated liver function tests, although they were resolved without treatment after Limbrel was stopped.

Limbrel Post-Marketing Surveillance (All Strengths) N = 294,399	(June 2011)	
	Incidence #	%
Allergy	2	0.001%
Angioedema		
Aspirin Intolerant Syndrome	1	0.000%
Aspirin Intolerant Syndrome		
Body as a Whole	32	0.011%
Fever (12), Chills (9), Flu Like Symptoms (6), Body Weakness (3), Flushing (2)		
Cardiovascular	10	0.003%
Heart Palpitations (4), Chest Pain (1), Increase in BP (3) Hypotension(1) Arrhythmia(1)		
Central Nervous System	18	0.006%
Dizziness (5), Headache (7), Confusion (1), Somnolence (1), Seizure (1) Auditory Hallucinations (1), Insomnia (2)		
Fluid Retention	4	0.001%
Edema (4)		
Hematology	1	0.000%
Polycythemia		
Hepatic	31	0.011%
Elevated Liver Function Tests (22), Jaundice (6), Hepatitis (3)		
Gastrointestinal	50	0.017%
Nausea/Upset (Sour) Stomach (17), Diarrhea (20), Flatulence (1), Bloating (1), Glossitis (1) Possible Upper GI Bleeding (3), Acid Reflux (2), Pancreatitis (2), Increase in IBS (1), Dark Stool (2)		
Gynecologic	8	0.003%
Spontaneous Abortion** (1), Menorrhagia/Vaginal Bleeding (3), Breast Pain (3), Hot Flashes (1)		
Musculoskeletal	23	0.008%
Joint Pain (12), Synovitis (4), Myalgia / Muscle Aches (7)		
Respiratory System	18	0.006%
Hypersensitivity Pneumonitis (11), Rapid Breathing (1), Dyspnea (5), Dyspepsia (1)		
Skin	22	0.007%
Rash (11), Hives (3), Itching (6), Bruising (2)		
Urinary System	1	0.000%
Incontinence		
Metabolic	1	0.000%
Blood Sugar Increase		
Total	222	0.1%

*Source: IMS Data, updated through June 2011

** Patient had numerous concomitant conditions and medications

To report side effects and/or adverse events, please call 480-483-1410.

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