

LIMBREL® Post-Marketing Surveillance (September 2017)



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

The table below lists the side effects reported by patients and physicians in post-marketing surveillance, as reported from introduction in 2004 through current date. Reported cases of rash and itching may have been associated with allergies to Limbrel's flavonoid ingredients and were transient in nature. Hypersensitivity pneumonitis is a rare, but serious complication of Limbrel therapy. Thus far, with more than 500,000 people exposed to the product, 40 cases of Hypersensitivity pneumonitis have been reported (31 confirmed and 18 unconfirmed). Of the reported cases of elevated liver tests most were mild and without symptoms. However, 73 cases were associated with clinical jaundice and higher elevated liver function tests. All resolved without treatment after Limbrel was stopped.

Limbrel Post-Marketing Surveillance (All Strengths) *N = 574,449	(Sept 2017) Incidence	
	#	%
Allergy	3	0.001%
Angioedema (2) Tongue Swelling (1)		
Aspirin Intolerant Syndrome	1	0.000%
Aspirin Intolerant Syndrome		
Body as a Whole	78	0.014%
Fever (38), Chills (15), Flu Like Symptoms (11), Body Weakness (5), Flushing (2) Dry throat (1) Cough (3) Dry Mouth (1) Nose Bleed (1) Dehydration (1)		
Cardiovascular	20	0.003%
Heart Palpitations (6), Chest Pain (2), Increase in BP, (5) Hypotension(2), Arrhythmia(2) Tachycardia (2), Syncopal Episode (1)		
Central Nervous System	44	0.008%
Dizziness/Vertigo (12), Headache (17), Confusion (2), Somnolence (1), Seizure (1) Auditory Hallucinations (2), Insomnia (4), Visual Changes (1), Anxiety (2), Narcolepsy (1), Paresthesia (1)		
Fluid Retention	8	0.001%
Edema (8)		
Hematology	2	0.000%
Polycythemia (1), Pancytopenia (1)		
Hepatic	87	0.015%
Elevated Liver Function Tests (69), Jaundice (12), Hepatitis (6)		
Gastrointestinal	128	0.022%
Nausea/Upset (Sour Stomach (33), Diarrhea (58), Flatulence (5), Bloating (3), Glossitis (1) Possible Upper GI Bleeding (3), Acid Reflux (6), Pancreatitis (2), Increase in IBS (1), Dark Stool (4) Indigestion(1) Abdominal Pain (7) Constipation (2) Rectal Bleeding (2)		
Gynecologic	9	0.002%
Spontaneous Abortion** (1), Menorrhagia/Vaginal Bleeding (3), Breast Pain (4), Hot Flashes (1)		
Musculoskeletal	34	0.006%
Joint Pain (15), Synovitis (4), Myalgia / Muscle Aches (14), Leg Cramps (1)		
Respiratory System	64	0.011%
Hypersensitivity Pneumonitis: Confirmed (31) and Unconfirmed (18), Rapid Breathing (1), Dyspnea (10), Dyspepsia (2), Asthma (1), Respiratory Failure (1)		
Skin	51	0.009%
Rash (25), Hives (5), Itching (17), Bruising (3), Hair Loss (1)		
Urinary System	1	0.000%
Incontinence		
Metabolic	1	0.000%
Blood Sugar Increase		
Neurological	1	0.000%
Stroke		
Misc.	4	0.001%
Allergic Reaction Unspecified		
Total	536	0.085%

*Source: IMS Data, updated through September 2017

** Patient had numerous concomitant conditions and medications

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