

LIMBREL[®] Post-Marketing Surveillance (December 2009)

(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 through December 2009. Reported cases of rash and itching may have been associated with allergies to Limbrel's flavonoid ingredients, were transient in nature, and occurred most often on the upper torso. One of the reported cases of heart palpitation occurred in a patient with a history of heart palpitation. The reported case of first trimester miscarriage occurred in a patient who was diagnosed with several concomitant conditions and was taking 7 prescription drugs (including 2 drugs with warnings against use during pregnancy) at the same time as taking LIMBREL. Therefore, it was unclear if the miscarriage was related to any one product or due to some other factor. Reported cases of elevated liver tests were all mild and without symptoms, except for one case associated with clinical jaundice, but all resolved without treatment after Limbrel was stopped.

Limbrel Post-Marketing Surveillance (All Strengths)	N = 234,543*	Incidence	
		#	%
Aspirin Intolerant Syndrome Aspirin Intolerant Syndrome		1	0.000%
Body as a Whole Fever (10), Chills (8), Flu Like Symptoms NFS (6), Hot Flashes (1), fatigue (2), Insomnia (1)		28	0.012%
Cardiovascular Recurring Heart Palpitation (3), Flushing (1), Chest Pain (1)		5	0.002%
Central Nervous System Dizziness(3), Headache(5), Light-Headedness(2), Confusion (1), Somnolence (1)		12	0.005%
Fluid Retention Edema		1	0.000%
Hematology Polycythemia		1	0.000%
Hepatic Elevated LFTs (16), Jaundice (1)		17	0.007%
Gastrointestinal Nausea (24), Diarrhea (11), Flatulence(1), Bloating(1), Glossitis(1), Upper GI Bleeding (1)		39	0.017%
Gynecologic First Trimester Miscarriage**(1), Vaginal Bleeding(1), Breast Pain (1)		3	0.001%
Musculoskeletal Joint Pain (11), Synovitis (5), Myalgia (4), Muscle Cramps (2)		22	0.009%
Respiratory System Hypersensitivity Pneumonitis (7), Pneumonia (1), Rapid Breathing (1), Dyspnea (1)		10	0.004%
Skin Rash (11), Hives(3), Itching (6), Bruising (1)		21	0.009%
Urinary System Increase in Pre-existing Incontinence		1	0.000%
Neurology Auditory Hallucinations (2)		2	0.001%
Metabolic Blood Sugar Increase		1	0.000%
Total		164	0.1%

*Source: Verispan VONA, updated in December 2009.

** Patient had numerous concomitant conditions and medications (see description above for further information).

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