

Listing of Treatment-Emergent Abnormal Lab Findings in Olanzapine-Treated Patients
 Placebo-Controlled F1D-MC-HGFU (Studies 1 and 2 Combined)
 (>= .4% Incidence, n > 1 in olanzapine treatment group, and > Incidence with Olanzapine than Placebo)

Treatment-Emergent Abnormal Findings	Placebo-Controlled F1D-MC-HGFU (Studies 1 and 2 Combined)						Criteria Met	Current Oral Category	Category for New Events from HGFU Acute Phase Database and/or upgrade	Rationale for Not Categorizing as Probably Causally Related (A) if any Criteria met in HGFU Database. Rationale for upgrading or categorizing new events
	Olz+MS			Plb+MS						
	N	n	%	N	n	%				
Labs										
Hematology										
Eosinophils - High	188	2	1.1%	94	0	0.0%	5	A	A	On Core Data Sheet
Platelet Count - Low	189	2	1.1%	93	0	0.0%	5	B	A	On Core Data Sheet - Thrombocytopenia
Clinical Chemistry										
ALT/SGPT - High	218	2	0.9%	112	0	0.0%	5	A	A	On Core Data Sheet
Creatine Phosphokinase - High	184	4	2.2%	98	1	1.0%	5	B	B	Total data do not support clear causality.
Glucose, Non-Fasting - High	185	4	2.2%	97	0	0.0%	5	A	A	On Core Data Sheet
Uric Acid - High	190	3	1.6%	100	0	0.0%	5	Not Categoriz ed in 1996 CPMP Response	B	Total data do not support clear causality.

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9/1/2004

Label Labs for Combined Bipolar Mania Submission .XLS

Category: A = Event probably causally related; B = causality of event uncertain; C = event probably not causally related