

Incidence of Potentially Clinically Significant Changes in Laboratory Analytes in Olanzapine-Treated Patients  
 Placebo-Controlled F1D-MC-HGHL  
 (>= .4% Incidence, n > 1 in olanzapine treatment group, and > Incidence with Olanzapine than Placebo)

Treatment-Emergent Abnormal Findings	F1D-MC-HGHL Placebo-Controlled Double-Blind Period						Criteria Met	Current Oral Category	Category for New Events from HGHL Database and/or upgrade	Rationale for Not Categorizing as Probably Causally Related (A) if any Criteria met in HGHL Database. Rationale for upgrading or categorizing new events
	Olz			Plb						
	N	n	%	N	n	%				
<b>Labs</b>										
<b>Clinical Chemistry</b>										
Glucose, Non-Fasting - High	207	3	1.4%	124	0	0.0%	5	A	A	In Core Data Sheet
Uric Acid - High	215	2	0.9%	127	1	0.8%	5	Not Categoriz ed in 1996 CPMP Response	B	Total Data do not support clear causality.
<b>Urinalysis</b>										
UA-Glucose - Increase>=2	155	2	1.3%	104	0	0.0%	5	B	A	In Core Data Sheet as Hyperglycemia

1  
9/1/2004

Label Labs for Bipolar Maintenance Submission .XLS

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