



U.S. Food and Drug Administration

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Safety

Zyprexa (olanzapine): Use in Adolescents

Audience: Neuropsychiatric healthcare professionals

[Posted 01/29/2010] Lilly and FDA notified healthcare professionals of changes to the Prescribing Information for Zyprexa related to its indication for use in adolescents (ages 13-17) for treatment of schizophrenia and bipolar I disorder [manic or mixed episodes]. The revised labeling states that:

Section 1, Indications and Usage: When deciding among the alternative treatments available for adolescents, clinicians should consider the increased potential (in adolescents as compared with adults) for weight gain and hyperlipidemia. Clinicians should consider the potential long-term risks when prescribing to adolescents, and in many cases this may lead them to consider prescribing other drugs first in adolescents.

Section 17.14, Need for comprehensive Treatment Program in Pediatric Patients: Zyprexa is indicated as an integral part of a total treatment program for pediatric patients with schizophrenia and bipolar disorder that may include other measures (psychological, educational, social) for patients with the disorder. Effectiveness and safety of ZYPREXA have not been established in pediatric patients less than 13 years of age.

[01/04/2010 - Dear Healthcare Professional Letter ¹ - Lilly] [12/2009 - Prescribing Information ² - Lilly]

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