



# Summary of investigation results

## Olanzapine

August 4, 2016

### Non-proprietary name

Olanzapine

### Brand name (Marketing authorization holder)

- a. Zyprexa Tablets 2.5 mg, 5 mg, 10 mg, Zyprexa Zydis Tablets 2.5 mg, 5 mg, 10 mg, Zyprexa Fine Granules 1% (Eli Lilly Japan K.K.) and others
- b. Zyprexa Intramuscular Injection 10 mg (Eli Lilly Japan K.K.)

### Indications

- a.
  - Schizophrenia
  - Improvement of manic and depressive symptoms in bipolar disorder
- b.
  - Psychomotor excitability in schizophrenia

### Summary of revision

“Drug-induced hypersensitivity syndrome (DIHS)” should be newly added in the Clinically significant adverse reaction section.

### Background of the revision and investigation results

The company core datasheet (CCDS)\* has been updated in response to the cases of drug-induced hypersensitivity syndrome in patients treated with olanzapine reported in Japan and overseas. In addition, the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) have taken action to alert caution for the syndrome. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

**The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 2 cases associated with drug-induced hypersensitivity syndrome have been reported (including a case for which a causal relationship to the product could not be ruled out). Of the 2 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be established for this patient).

**Note:**

\*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.