

Current	Revision Draft
<p>WARNINGS Nil</p> <p>CONTRAINDICATIONS 1. 2. 3. 4.</p> <p>PRECAUTIONS 1. Careful Administration 1. ~ 5. (omit)</p> <p>2. Important Precautions 1. 2. 3. 4. 5.</p>	<p>WARNINGS 1. <u>Accompanying marketed increase in blood glucose, Upon administration of olanzapine, serious adverse reactions such as diabetic ketoacidosis, diabetic coma etc. may appear accompanying marketed increase in blood glucose, leading potentially to death. Observe sufficiently including measurement of blood glucose during the olanzapine administration.</u> 2. <u>Upon administration, explain sufficiently in advance to patients and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent urination, etc., and to see a physician suspending administration immediately and advise that if such symptoms appear, discontinue administration immediately and see a physician.</u> <u>See the section on “Important Precautions”</u></p> <p>CONTRAINDICATIONS 1. 2. 3. 4. 5. <u>Patients with diabetes mellitus and those who have a history of diabetes mellitus</u></p> <p>PRECAUTIONS 1. Careful Administration 1. ~ 5. (omit) 6. <u>Patients with risk factors for diabetes mellitus such as family history of diabetes mellitus, hyperglycemia, obesity, etc. (See the section on “Important Precautions”).</u></p> <p>2. Important Precautions 1. <u>ByUpon administration of this drug, marked increase in blood glucose may appear leading to fatal clinical course such as diabetic ketoacidosis, diabetic coma, etc. Observe sufficiently</u> <u>Observe sufficiently including measurement of blood glucose during the olanzapine administration. In</u></p>

<p>4. Adverse Reactions (1) Clinically significant adverse reactions 1. Syndrome maline 2. Tardive dyskinesia: 3. Hyperglycemia:</p>	<p><u>particular, patients with risk factors for diabetes mellitus such as hyperglycemia, obesity, etc., blood glucose may increase, leading to acute worsening of metabolic state.</u></p> <p>2. <u>Upon administration, explain sufficiently in advance to patients and family members possible occurrence of above adverse reactions. Provide guidance to them to pay attention to such abnormalities as thirst, polydipsia, polyurea, frequent frequent urination, etc., and to see a physician advise suspending administration immediately, that if such symptoms appear, discontinue administration immediately and see a physician.</u></p> <p>1.→3. As olanzapine may increase body weight, pay attention to obesity, and <u>take appropriate measures</u> such as the diet therapy and exercise therapy, etc. if any sign of obesity is noted. 2. Delete 3. ~5. →4. ~ 6.</p> <p>4. Adverse Reactions (1) Clinically significant adverse reactions 1. Hyperglycemia, <u>Diabetic ketoacidosis, Diabetic coma: Hyperglycemia may develop leading to fatal clinical course, such as diabetic ketoacidosis and diabetic coma leading to death. Thus, make a close observation, with such as blood glucose measurement, (appearance of) thirst, polydipsia, polyurea, frequent urination. If any abnormalities are noted, discontinue administration and take an appropriate measure(s) including administration of insulin.</u> 2. Syndrome malin: 3. Tardive dyskinesia:</p>
--	---