

Hyperglycaemia Inclusion in EU SPC

Only relevant hyperglycaemia / diabetes text is included:

Submitted	Approved (Implementation date)	Section 4.4 Special warnings and special precautions for use:	Section 4.8 Undesirable effects:
23/12/98 Type II variation	19/07/99 (no info)	Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases during ZYPREXA treatment. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus.	Rare (<1%): Hyperglycaemia or exacerbation of pre-existing diabetes has been reported in very rare cases (see also Section 4.4, Special warnings and special precautions for use).
19/06/00 Type II variation	28/12/00 (from Dec-00)	<i>Text moved to top of section and modified:</i> Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been reported very rarely, including some fatal cases. In some cases, a prior increase in body weight has been reported which may be a predisposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus.	Common (1-10%): Non-fasting plasma glucose levels ≥ 11 mmol/l (suggestive of diabetes) as well as non-fasting levels ≥ 8.9 mmol/l but < 11 mmol/l (suggestive of hyperglycemia) in patients with baseline non-fasting glucose levels ≤ 7.8 mmol/l have been seen occasionally in clinical trials. Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been spontaneously reported very rarely, including some fatal cases (see also Section 4.4, Special warnings and special precautions for use).
05/12/00 Type II variation	14/06/01 (mid Jul to mid Oct 01)	<i>No change</i>	Common (1-10%): In clinical trials with olanzapine in over 5000 patients with baseline non-fasting glucose levels ≤ 7.8 mmol/l, the incidence of non-fasting plasma glucose levels ≥ 11 mmol/l (suggestive of diabetes) was 1.0%, compared to 0.9% with placebo. The incidence of non-fasting plasma glucose levels ≥ 8.9 mmol/l but < 11 mmol/l (suggestive of hyperglycaemia) was 2.0%, compared to 1.6% with placebo. For further information, see Section "Very Rare (<0.01%)" below. Very Rare (<0.01%): Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been

			spontaneously reported very rarely, including some fatal cases (see also Section 4.4, Special warnings and special precautions for use).
Renewal 22/05/01	20/11/01 (Currently approved) (Jan-02 to mid Mar-02)	<i>No change</i>	<p><i>Information put into two tables as below:</i></p> <p>The following table of undesirable effects is based on adverse event reporting and laboratory investigations from clinical trials.</p> <p>Metabolism and nutrition disorders <i>Common (1-10%):</i> Elevated glucose levels (see note 1 below).</p> <p>¹In clinical trials with olanzapine in over 5000 patients with baseline non-fasting glucose levels ≤ 7.8 mmol/l, the incidence of non-fasting plasma glucose levels ≥ 11 mmol/l (suggestive of diabetes) was 1.0%, compared to 0.9% with placebo. The incidence of non-fasting plasma glucose levels ≥ 8.9 mmol/l but < 11 mmol/l (suggestive of hyperglycaemia) was 2.0%, compared to 1.6% with placebo. Hyperglycaemia is also reported as a Very Rare ($<0.01\%$) spontaneous event.</p> <p>The following table of undesirable effects is based on post-marketing spontaneous reports.</p> <p>Metabolism and nutrition disorders <i>Very rare ($<0.01\%$):</i> Hyperglycaemia or exacerbation of pre-existing diabetes occasionally associated with ketoacidosis or coma has been spontaneously reported very rarely, including some fatal cases (see also Note 1 above and Section 4.4, Special warnings and special precautions for use).</p>

Approved = Date of Commission Decision Implementation date = date printed matter appeared in the pack on the market place