

VARIATION	FILED	CPMP OPINION	COMMISSON DECISION (ie Approval to implement in pack)	Description of change
<p>Safety variation to SPC/PL</p> <p><i>Zyprexa 2.5, 5, 7.5, 10 mg</i>  <i>Olansek 2.5, 5, 7.5, 10 mg</i>  <i>Zyprexa Velotab 5, 10, 15, 20 mg</i></p>	19 June 00	21 Sep 00	28 Dec 00	<p>Safety variation at CPMP request. On SPC:.</p> <ol style="list-style-type: none"> <li>1. Paragraph on hyperglycaemia moved to top of section 4.4; added terms acidosis and coma</li> <li>2. Reference made to cases of hepatitis with advice for discontinuation added to section 4.4.</li> <li>3. Term “peripheral” is deleted before “oedema” under Section 4.8</li> <li>4. Hyperglycaemia information moved from under “Rare&lt;1%” to “Occasional 1-10%”</li> <li>5. Section 4.9, overdose information rewritten in line with clinical experience.</li> </ol> <p>On package leaflet, information on diabetes moved to top of relevant section – other SPC driven changes.</p>
<p>Safety variation to SPC/PL</p> <p><i>Zyprexa 2.5, 5, 7.5, 10, 15, 20 mg</i>  <i>Olansek 2.5, 5, 7.5, 10 mg</i>  <i>Zyprexa Velotab 5, 10, 15, 20 mg</i></p>	5 Dec 00	28 Feb 01	<p>(Z) 14 Jun 01  (O) 8 Jun 01  (V) 14 Jun 01</p>	<p>Changes to Section 4.8 of SPC:  Clarification of clinical trial information on hyperglycaemia. Introduced CIOMS category (&lt;0.01% very rare) for spontaneous reports of hyperglycaemia (with/without ketoacidosis or coma), hepatitis and priapism.</p>