<table>
<thead>
<tr>
<th>VARIATION</th>
<th>FILED</th>
<th>CPMP OPINION</th>
<th>COMMISSION DECISION (ie Approval to implement in pack)</th>
<th>Description of change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety variation to SPC/PL</td>
<td>19 June 00</td>
<td>21 Sep 00</td>
<td>28 Dec 00</td>
<td>Safety variation at CPMP request. On SPC:</td>
</tr>
<tr>
<td>Zyprexa 2.5, 5, 7.5, 10 mg</td>
<td></td>
<td></td>
<td></td>
<td>1. Paragraph on hyperglycaemia moved to top of section 4.4; added terms acidosis and coma</td>
</tr>
<tr>
<td>Olansek 2.5, 5, 7.5, 10 mg</td>
<td></td>
<td></td>
<td></td>
<td>2. Reference made to cases of hepatitis with advice for discontinuation added to section 4.4</td>
</tr>
<tr>
<td>Zyprexa Velotab 5, 10, 15, 20 mg</td>
<td></td>
<td></td>
<td></td>
<td>3. Term “peripheral” is deleted before “oedema” under Section 4.8</td>
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<td></td>
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<td></td>
<td>4. Hyperglycaemia information moved from under “Rare&lt;1%” to “Occasional 1-10%”</td>
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<td>5. Section 4.9, overdose information rewritten in line with clinical experience.</td>
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<td>On package leaflet, information on diabetes moved to top of relevant section – other SPC driven changes</td>
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<tr>
<td>Safety variation to SPC/PL</td>
<td>5 Dec 00</td>
<td>28 Feb 01</td>
<td>(Z) 14 Jun 01 (O) 8 Jun 01 (V) 14 Jun 01</td>
<td>Changes to Section 4.8 of SPC:</td>
</tr>
<tr>
<td>Zyprexa 2.5, 5, 7.5, 10, 15, 20 mg</td>
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<td></td>
<td>Clarification of clinical trial information on hyperglycaemia.</td>
</tr>
<tr>
<td>Olansek 2.5, 5, 7.5, 10 mg</td>
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<td></td>
<td>Introduced CIOMS category (&lt;0.01% very rare) for spontaneous reports of hyperglycaemia (with/without ketoacidosis or coma), hepatitis and priapism.</td>
</tr>
</tbody>
</table>