## SPC (Product Licence) Changes

### Record Details

<table>
<thead>
<tr>
<th>Title</th>
<th>Linezolid (Zyvox 600 mg Film-Coated Tablets, 100 mg/5 ml Granules for Oral Suspension, 2 mg/ml Solution for Infusion) - revised SPC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Published</td>
<td>12/03/2007</td>
</tr>
<tr>
<td>Type of SPC change</td>
<td>Revised SPC</td>
</tr>
<tr>
<td>Generic drug name</td>
<td>Linezolid</td>
</tr>
<tr>
<td>Drug brand name</td>
<td>Zyvox</td>
</tr>
<tr>
<td>Legal status</td>
<td>POM - Black Triangle</td>
</tr>
<tr>
<td>Pharmaceutical manufacturer</td>
<td>Pharmacia Ltd</td>
</tr>
</tbody>
</table>

### Abstract

The SPC has been updated. Section 4.1 (therapeutic indications) has been amended to state that for community acquired and nosocomial pneumonia, linezolid is not active against infections caused by Gram negative pathogens. Specific therapy against Gram negative organisms must be initiated concomitantly if a Gram negative pathogen is documented or suspected. Also, Zyvox is indicated for the treatment of complicated skin and soft tissue infections only when microbiological testing has established that the infection is known to be caused by susceptible Gram positive bacteria. Section 4.4 now contains the warning that in complicated skin and soft tissue infections linezolid should only be used in patients with known or possible co-infection with Gram negative organisms if there are no alternative treatment options available. In these circumstances treatment against Gram negative organisms must be initiated concomitantly. The statement that linezolid has in vitro activity against some Gram negative bacteria has been removed from section 5.1.

### Resource Links

- SPC

### Date on SPC

28 February 2007

### Categories

- BNF Category > 5: Infections > 5.1 Antibacterial drugs > 5.1.7 Some other antibacterials
- Medical Specialty > Infections > Bacterial