Defending Zyprexa on Hyperglycaemia/Diabetes

Key Messages

Glossary of Terms:

Hyperglycaemia
raised blood sugar levels over a sustained period of time – in the general population, return to normal levels occurs naturally

Diabetes II Mellitus
raised blood sugar levels at or above 200 mg/dL / 11.1 mmol. Diabetics need intervention to lower blood sugar levels

First response:

Schizophrenia and Diabetes

• One in six people with schizophrenia have an increased risk of developing diabetes\(^2\). In fact, the prevalence of diabetes is two to four times greater in these patients and the risk increases with age\(^2\)
• Hyperglycaemia/diabetes is more likely to be a result of schizophrenia than any other factor – it is a 'disease' effect\(^2\)
• With good disease management, including advice on lifestyle, the risk of hyperglycaemia/diabetes associated with schizophrenia is likely to be reduced

If pushed on Zyprexa specific data:

Zyprexa, Hyperglycaemia and Diabetes

• Being diagnosed with hyperglycaemia is not necessarily an indication of a definite progression to diabetes
• More than 6 million people have taken Zyprexa worldwide
• Zyprexa is a very effective treatment for a life-threatening disease
• Large scale data analysis does not support a sustained risk of treatment-emergent hyperglycaemia or diabetes with Zyprexa in comparison to other typical and atypical antipsychotics and to placebo\(^5\)
• Stopping medication for schizophrenia is likely to be much more serious (possibly resulting in suicide) than any potential risk from these drugs and hyperglycaemia

Zyprexa, Hyperglycaemia and Weight Gain

• In large scale data analysis, 95% of patients on Zyprexa who even gained as much as 10% in weight did not show an increased likelihood of elevated glucose levels which indicates diabetes\(^3\)
• There has been no definitive association between weight gain with Zyprexa and hyperglycaemia\(^4\)
• Weight is increasing in the general population as a whole and everyone should be given advice on diet and exercise. In people with schizophrenia it is important to treat the whole person not just the primary disease
• Early disease is key to managing the all round health of someone with schizophrenia

References:
1. American Diabetes Association. Screening for Type 2 Diabetes (position statement). Diabetes Care 2000;23(S1)
3. Allison/Beasley et al, Comparing Glycemic Profiles Across Treatment Options in Psychiatric Disorders, Data on File
Zyprexa Product Team
2001 Priorities

- Manage Weight Gain / Hyperglycemia
- Competitive Blunting and Differentiation
  - focus on Zeldox, Risperdal
- The Bipolar Patient
  - mania, maintenance, \[\text{Redacted}\]
- The Acutely Ill Patient
  - IM, high dose, Zydis
- The Chronically Ill Patient
  - depot, relapse prevention
- Brand Strategy
  - position, health outcomes, pricing

Lilly
Answers That Matter.
# Team Structure

<table>
<thead>
<tr>
<th>Mood</th>
<th>Acute</th>
<th>Maintenance</th>
<th>Safety</th>
<th>Competitive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agitated patients (schizo., mania, and dementia)</td>
<td>Relapse prevention</td>
<td>Glycemia &amp; weight clinical plans</td>
<td>Differentiation (risperidone, quetiapine, valproate...)</td>
<td>Zeldox blunting</td>
</tr>
<tr>
<td>Depression</td>
<td>RAIM</td>
<td>Depot</td>
<td>Regulatory response</td>
<td>Health Outcomes</td>
</tr>
<tr>
<td>Positioning</td>
<td>1st Episode, Prodromal</td>
<td>Health outcomes</td>
<td>Core data sheet</td>
<td></td>
</tr>
<tr>
<td>Health outcomes</td>
<td>High dose, onset of act.</td>
<td>Scientific comm. plan</td>
<td>Health Outcomes</td>
<td></td>
</tr>
<tr>
<td>Scientific comm. plan</td>
<td>Health outcomes</td>
<td>Scientific comm. plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scientific comm. plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TL = Sub Team Leader  
MED = Primary Medical Contact  
MKTG = Primary Marketing Contact