Zydis® fast-dissolve case study

Zelapar® Zydis Fast-Dissolve formulation
Introduction: Parkinson’s Market
Zelapar Launched Into A Mature, Generic Market

Selegiline Market Landscape

Traditional Formulations
- Eldepryl® (June, 1989)
- Generic Selegiline (June, 1997)

FDA Approval History
- 1989-1996
- 1997-2003
- 2004-2005
- 2006-2007
- 2008-2011

Orally Disintegrating Tablet (ODT) Formulations
- Parcopa® ODT (August, 2004)
- Zelapar® formulated with Zydis® fast-dissolve (June, 2006)
- Generic ODT Selegiline (Sept, 2008)

Selegiline: Class of dopaminergic antiparkinsonism agents, used in addition to carbidopa/levodopa agents, in the treatment of Parkinson’s Disease

Zelapar: Once daily dosed Selegiline HCL formulated with Zydis® fast-dissolve technology, marketed by Valeant Pharmaceuticals International, Inc.

Zydis Fast-Dissolve: Orally disintegrating tablet (ODT) that disperses instantly (usually <3 seconds) in the mouth, developed and manufactured by Catalent Pharma Solutions
## Summary of Zydis Fast-Dissolve Impact on Product Profile

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<th>Tablet/Capsule Selegiline (traditional formulation)</th>
<th>Zelapar formulated with Zydis fast-dissolve (innovative formulation)</th>
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<tbody>
<tr>
<td><strong>Lower Dose and Less Frequent Dosing</strong></td>
<td>5-mg doses, taken twice a day (BID). Pill or capsule that must be swallowed.</td>
<td>1.25-mg or 2.5-mg doses, taken once a day (QD). Tablet that dissolves in mouth within seconds, without water.</td>
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<td><strong>Increased Bioavailability/Faster Onset of Action</strong></td>
<td>Tmax=1 hour. Digested in the gut, adsorbed through the small intestine, processed by the liver.</td>
<td>Tmax=15 minutes. Innovative transmucosal drug delivery adsorbed rapidly through the lining of the mouth directly into the blood.</td>
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<td><strong>Lower Side Effect Potential</strong></td>
<td>Processed through the liver, producing undesired metabolites.</td>
<td>Significantly by-passes the liver, producing lower undesired metabolites.</td>
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Zydis fast-dissolve enabled Zelapar to deliver: MORE drug where needed, safer and faster.
Zydis Fast-dissolve Formulation Shows Higher Patient Compliance Rates

Zydis fast-dissolve formulation has highest Patient Compliance for Medicare Parkinson’s Disease market, based on 12 month longitudinal patient records analysis.

2010 Selegiline Market Size: $19.3M
1% increase in compliance = $200K
Value added to healthcare system

Zelapar, Age: Total, Gender: Total, Pay Type: Medicare
Data Source: SDI Health Patient Data, 2011

Additional Cohort Compliance Improvements:
- All Ages, Female, All Payers: Zelapar 91.6%, Selegiline 83.7%
- Age 19-65, All genders, All Payers: Zelapar 87.3%, Selegiline 83.8%
Zelapar (Zydis Fast-dissolve) Launched Into A Generic Market And Experienced Substantial Sales Growth

**US Sales – Selegiline Class: Anti-Parkinson Market**

Data Source: IMS Health, 2010

- Zelapar (Zydis) 5 year $ CAGR: 95.9%
- Eldepryl (non-ODT branded) 6 year $ CAGR: -12.7%
- Selegiline Generics 6 year $ CAGR: 15.8%
Zelapar (Zydis Fast-dissolve) Captured The ODT Market Share Leader Position & Retained Post ODT Generic Entry

**US ODT Share ($): Anti-Parkinson Market**

- **Pre-Generic ODT High Share Gain**
- **Post-Generic ODT High Share Retention**

2010 Market Share:  Zelapar (50.1%)  Parcopa (27.6%)  Mylan Generic (20.2%)  Sun Generic (2.1%)

Data Source: IMS Health, 2010

Zelapar (Zydis fast-dissolve) has captured 2X the market share of branded ODT’s and retained 2.5X share of generic ODT’s.
Zelapar (Zydis Fast-Dissolve) vs. Non-Zydis Fast-Dissolve Selegiline

**Better Products = Market Impact**

- Zydis fast-dissolve differentiated Zelapar’s product profile from competition
- Zydis fast-dissolve showed improved compliance for Medicare patients
  - 83% of patients preferred Zydis fast dissolve vs. traditional tablets in other therapeutic areas (antihistamine patient preference study; n-420)
- Zydis fast-dissolve successfully launched into already generic market with very positive share gains
- Zydis fast-dissolve significantly outperformed BOTH branded and generic non-ODT competition in sales growth rates
- Zydis fast-dissolve is the dominant market leader in ODT products, gaining vs. branded and retaining vs. generic market share
Zydis fast-dissolve technology has demonstrated Positive Market Share, Sales Growth, and Brand Retention Rates across the following Therapeutic Areas:

- Parkinson’s Disease
  - CNS
  - GI
- Allergy
- Nausea (Emesis)
- Migraine
- Pain
Zydis Fast-dissolve: Enhance The Value Of Your Investment With A Differentiated ODT

**Brand and Product Life Cycle Management**
- Proven commercial success of ODT line extensions and launches
- 20 Zydis products launched in over 60 countries
- Select shape and embossing to reinforce branding and avoid counterfeiting

**Patient Convenience**
- Fast dissolve ODT disperses in less than 3 seconds compared to up to 30 seconds for loosely compressed ODTs
- Robust tablet in a convenient blister pack, calendar pack
- Taken without water-on the go
- Enhance brand loyalty

**Patient Compliance**
- Manage patients who cannot or will not take oral medications
- Avoid expulsion or “cheeking” of oral medications
- Taste masking and flavors to meet patient needs

**Potential for Enhanced Pharmacokinetics**
- Potential for lower dose, improved bioavailability or reduced side effects
- Development team ready to evaluate potential candidates for buccal absorption
Discover how Catalent can help differentiate your products.

To discuss solutions to your challenges, please click on the Challenge Us link below:

CATALENT PHARMA SOLUTIONS
14 SCHOOLHOUSE ROAD
SOMERSET, NJ 08873
+ 1 866 720 3148
www.catalent.com

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