



## Therapeutic Class Review<sup>SM</sup>

### Neurology – Rotigotine Transdermal System (Neupro<sup>®</sup>)

December 2007

#### New Product for Review:

Rotigotine transdermal system (Neupro<sup>®</sup>)  
[UCB/Schwarz Pharma]

#### Dossier Provided by Manufacturer:

##### Dossier Evaluation: 2

- 1 - Dossier missing significant clinical trial(s).
- 2 - Mfg. provided all relevant trials; Missing pharmacoeconomic model.
- 3 - Mfg. provided all relevant trials and information.

#### Executive Summary

- Parkinson's disease (PD) a neurodegenerative disorder.
  - Classic symptoms include:
    - Bradykinesia
    - Rigidity
    - Rest tremor
  - Incidence ~ 13/100,000
  - Prevalence ~ 300/100,000
  - Prevalence of PD is rising slowly with aging population.
- Rotigotine (Neupro) is indicated for the treatment of early-stage idiopathic Parkinson's disease.
  - Rotigotine transdermal system (Neupro) is a topical patch that provides a continuous 24-hour supply of rotigotine.
  - Rotigotine is a non-ergolinic dopamine agonist active at the D1, D2, and D3 dopamine receptors.
  - There are ongoing studies in restless legs syndrome (RLS) and advanced Parkinson's disease.
- Rotigotine (Neupro) has been available in Europe for several years and is indicated there for advanced PD and RLS, as well as early PD.
  - Two large phase-III US trials examining the use of rotigotine (Neupro) in patients with RLS were recently presented at the AAN conference.
  - The manufacturer has been unable to provide this data despite repeated requests.
  - It is likely that rotigotine (Neupro) will be used off-label for RLS and advanced PD.

#### Evidence

- There is no useful evidence that rotigotine (Neupro):
  - Provides superior safety or efficacy than other formulary dopamine agonists for the treatment of early PD.

- Results in improved compliance or persistence than other formulary dopamine agonists for the treatment of early PD.
- Is effective for indications other than early PD.

### Decision

Rotigotine (Neupro) is non-preferred/non-formulary because:

- It provides no proven benefit over current preferred/formulary alternatives.
- There appears to be an increased potential for adverse events related to application site reactions and other skin reactions.

### Products<sup>12</sup>

Drug Products	FDA approval <sup>a</sup>	Patent Expiration(s) <sup>d</sup>	FDA approved indications	Usual Dose/Route	Potential Off-label Uses <sup>c</sup>
<b>MAO B Inhibitors</b>					
selegiline (generic)	06/1989	N/A	- Parkinson's disease; Adjunct	5mg bid PO	- Alzheimer's disease – Dementia - Attention deficit hyperactivity disorder - Dementia – HIV infection - Depression - Narcolepsy - Parkinson's disease, initial treatment - Periodic limb movement disorder - Schizophrenia; Adjunct
rasagiline (Azilect)	05/2006	2016	- Parkinson's disease - Parkinson's disease; Adjunct	1mg qd PO	- None noted
<b>Dopamine Agonists</b>					
pramipexole (Mirapex <sup>®</sup> )	07/1997	2011	- Parkinson's disease - Parkinson's disease; Adjunct - Restless legs syndrome	1mg tid	- Depression - Panic disorder - Schizophrenia
ropinirole (Requip <sup>®</sup> )	09/1997	May 2008	- Parkinson's disease - Parkinson's disease; Adjunct - Restless legs syndrome	2mg tid	- None noted
bromocriptine (generic)	06/1978	N/A	- Parkinson's disease - Parkinson's disease; Adjunct - Acromegaly - Hyperprolactinemia-Associated Dysfunctions	10 mg tid	- Numerous
rotigotine (Neupro <sup>®</sup> )	05/2007	2019	- Early Parkinson's	4 mg to 6 mg applied daily.	- None noted

			disease		
<b>COMT Inhibitors</b>					
tolcapone (Tasmar <sup>®</sup> )	01/1998	2012	- Parkinson's disease; Adjunct	100mg tid	- Depression
entacapone (Comtan <sup>®</sup> )	10/1999	2009	- Parkinson's disease; Adjunct	200mg with each dose of levodopa (3 to 8 times daily)	- Restless legs syndrome

<sup>a</sup> Date applies to approval date for the original brand name medication where there are now generics available.

<sup>c</sup> As listed in © 1974 - 2007 Thomson MICROMEDEX database or as referenced.

<sup>d</sup> Based on patents listed in Orange Book as of November 2007

## References

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