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Trial record **1 of 1** for: CENA713B2315

Previous Study | Return to List | Next Study

Long-term Safety of Rivastigmine Capsule and Patch in Patients With Mild to Moderately-severe Dementia Associated With Parkinson's Disease (PDD)

This study has been completed.

Sponsor:
Novartis

Information provided by (Responsible Party):
Novartis

ClinicalTrials.gov Identifier:
NCT00623103

First received: February 14, 2008
Last updated: October 19, 2011
Last verified: October 2011
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: October 19, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Parkinson's Disease Dementia
Interventions:	Drug: Rivastigmine capsule Drug: Rivastigmine transdermal patch

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Participant Flow: Overall Study

	Rivastigmine Capsule	Rivastigmine Patch
STARTED	**295**	**288**
Safety Set: Received Study Drug	**294** [1]	**288**
COMPLETED	**184**	**175**
NOT COMPLETED	**111**	**113**
Adverse Event	**70**	**60**
Unsatisfactory therapeutic effect	**4**	**12**
Withdrawal by Subject	**18**	**24**
Lost to Follow-up	**4**	**1**

Administrative problems	**2**	**4**
Death	**11**	**11**
Protocol deviation	**2**	**1**

[1] One randomized participant did not receive study drug and was not included in the Safety set.

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.
Total	Total of all reporting groups

Baseline Measures

	Rivastigmine Capsule	Rivastigmine Patch	Total
Number of Participants [units: participants]	**295**	**288**	**583**
Age [units: years]	**72.35 (6.295)**	**72.26 (6.352)**	**72.31 (6.318)**

Mean (Standard Deviation)			
Gender [units: participants]			
Female	**88**	**97**	**185**
Male	**207**	**191**	**398**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Adverse Events (AEs) Due, or Potentially Due, to Worsening of Parkinson Disease (PD) Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall) [Time Frame: 76 Weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Adverse Events (AEs) Due, or Potentially Due, to Worsening of Parkinson Disease (PD) Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall)
Measure Description	The AEs were summarized by presenting the number and percentage of patients having any of the 4 AEs or discontinued due to any of the 4 predefined AEs (tremor, muscle rigidity, bradykinesia, and fall)in each treatment group. The 95% CIs associated with the rates were also presented.
Time Frame	76 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety Population consisted of all participants who received at least 1 dose of study drug and had 1 post-baseline safety measurement. Participants with observation at 76 weeks were included in this analysis.

Reporting Groups

	Description

Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	Rivastigmine Patch
Number of Participants Analyzed **[units: participants]**	**294**	**288**
Percentage of Participants With Adverse Events (AEs) Due, or Potentially Due, to Worsening of Parkinson Disease (PD) Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall) **[units: Percentage of participants]** **Number (95% Confidence Interval)**		
Tremor	**24.5** **(19.7 to 29.8)**	**9.7** **(6.6 to 13.7)**
Muscle Rigidity	**4.1** **(2.1 to 7.0)**	**5.2** **(2.9 to 8.4)**
Bradykinesia	**5.1** **(2.9 to 8.3)**	**6.3** **(3.7 to 9.7)**
Fall	**17.0** **(12.9 to 21.8)**	**20.1** **(15.7 to 25.2)**

No statistical analysis provided for Percentage of Participants With Adverse Events (AEs) Due, or Potentially Due, to Worsening of Parkinson Disease (PD) Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall)

2. Primary: Percentage of Participants With Study Drug Discontinuations Due to Predefined AEs That Are Due, or Potentially Due, to Worsening of PD Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall) [Time Frame: 76 Weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Study Drug Discontinuations Due to Predefined AEs That Are Due, or Potentially Due, to Worsening of PD Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall)
Measure Description	The discontinuations due to these AEs were summarized by presenting the number and percentage of patients having any of the 4 AEs or discontinued due to any of the 4 predefined AEs (tremor, muscle rigidity, bradykinesia, and fall) in each treatment group. The 95% CIs associated with these rates were also presented.
Time Frame	76 Weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety Population consisted of all participants who received at least 1 dose of study drug and had 1 post-baseline safety measurement. Participants with observation at 76 weeks were included in this analysis.

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	**Rivastigmine Patch**

Number of Participants Analyzed **[units: participants]**	**294**	**288**
Percentage of Participants With Study Drug Discontinuations Due to Predefined AEs That Are Due, or Potentially Due, to Worsening of PD Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall) **[units: Percentage of participants]** **Number (95% Confidence Interval)**		
Tremor	**2.4** **(1.0 to 4.8)**	**0.7** **(0.1 to 2.5)**
Muscle Rigidity	**0.3** **(0.0 to 1.9)**	**0.3** **(0.0 to 1.9)**
Bradykinesia	**1.0** **(0.2 to 3.0)**	**0.0** **(0.0 to 0.0)**
Fall	**1.0** **(0.2 to 3.0)**	**1.4** **(0.4 to 3.5)**

No statistical analysis provided for Percentage of Participants With Study Drug Discontinuations Due to Predefined AEs That Are Due, or Potentially Due, to Worsening of PD Motor Symptoms (Tremor, Muscle Rigidity, Bradykinesia, Fall)

3. Secondary: Change in Unified Parkinson Disease Rating Scale (UPDRS) Part III Motor Examination Scores at Weeks 8, 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline [Time Frame: From Baseline to Weeks 8, 16, 24, 52 and 76]

Measure Type	Secondary
Measure Title	Change in Unified Parkinson Disease Rating Scale (UPDRS) Part III Motor Examination Scores at Weeks 8, 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline
Measure Description	Unified Parkinson Disease Rating Scale (UPDRS) is a 6 part Parkinson's disease specific rating scale that estimates clinical function taking into consideration both disability (functional deficits) and impairment (objective clinical signs). Part III records the motor examination in Items 18-31 rated on a scale of 0 to 4 with (0 being absent/ normal and 4 being the worse) for a total possible score of 0 to 56.
Time Frame	From Baseline to Weeks 8, 16, 24, 52 and 76
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population consisted of all participants who received at least 1 dose of study drug and had 1 post-baseline safety measurement. "n" in each of the categories is the number of participants at each time point with non-missing baseline and post-baseline measurements.

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	**Rivastigmine Patch**
Number of Participants Analyzed **[units: participants]**	**294**	**288**
Change in Unified Parkinson Disease Rating Scale (UPDRS) Part III Motor Examination Scores at Weeks 8, 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline **[units: Score on a scale]** **Mean (Standard Deviation)**		
Week 8 (n=276,277)	**-0.4 (6.99)**	**-0.9 (7.05)**
Week 16 (n=254,252)	**0.5 (7.72)**	**-1.7 (7.44)**
Week 24 (n=229,237)	**0.1 (8.19)**	**-1.4 (7.90)**
Week 52 (n=203,206)	**0.7 (8.66)**	**1.6 (9.57)**
Week 76 (n=183,175)	**2.1 (9.98)**	**2.1 (9.65)**

No statistical analysis provided for Change in Unified Parkinson Disease Rating Scale (UPDRS) Part III Motor Examination Scores at Weeks 8, 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline

4. Secondary: Change in Mattis Dementia Rating Scale (Mattis DRS-2) Scores at Weeks 16, 24, 52 and 76 Compared to Baseline [Time Frame: From Baseline to Weeks 16, 24, 52 and 76]

Measure Type	Secondary
Measure Title	Change in Mattis Dementia Rating Scale (Mattis DRS-2) Scores at Weeks 16, 24, 52 and 76 Compared to Baseline
Measure Description	Mattis DRS-2 is a measure of cognitive status. The total score is the sum of 5 subscale scores: Attention [0-37], Initiation/Perservation [0-37] (performing alternating movements), Construction [0-6] (copying designs), Conceptualization [0-39] (similarities) and Memory [0-25] (sentence recall, design recognition)for a total possible score of 0-144. Higher score is reflective of better cognitive function, lower scores associated with more pronounced cognitive deficit. The change from baseline was calculated such that a positive number indicates an improvement.
Time Frame	From Baseline to Weeks 16, 24, 52 and 76
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population which included all patients who received at least 1 dose of study drug and had at least 1 pre- and post-baseline assessment for 1 of the efficacy variables. Last observation carried forward. (LOCF)

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	Rivastigmine Patch
Number of Participants Analyzed **[units: participants]**	**273**	**273**
Change in Mattis Dementia Rating Scale (Mattis DRS-2) Scores at Weeks 16, 24, 52 and 76 Compared to Baseline **[units: Score on a scale]** **Mean (Standard Deviation)**		
Week 16	**5.4 (11.98)**	**3.4 (11.53)**
Week 24	**6.5 (12.98)**	**4.4 (12.85)**
Week 52	**4.6 (13.62)**	**1.3 (15.07)**
Week 76	**3.9 (16.82)**	**-1.4 (17.43)**

No statistical analysis provided for Change in Mattis Dementia Rating Scale (Mattis DRS-2) Scores at Weeks 16, 24, 52 and 76 Compared to Baseline

5. Secondary: Change in Ten Point Clock Test (TPCT) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline [Time Frame: From Baseline to Weeks 16, 24, 52 and 76]

Measure Type	Secondary
Measure Title	Change in Ten Point Clock Test (TPCT) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline
Measure Description	The Ten Point Clock Test measures executive functioning and visuospatial skills. Participants are asked to put numbers on the face of a clock and then make the clock read 10 minutes after 11. Points are awarded on a scale of 0 to 10 for spacing of specific numbers and the positions of the hands. The change from baseline was calculated such that a positive number indicates improvement.
Time Frame	From Baseline to Weeks 16, 24, 52 and 76
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population which included all patients who received at least 1 dose of study drug and had at least 1 pre- and post-baseline assessment for 1 of the efficacy variables. Last observation carried forward. (LOCF)

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	**Rivastigmine Patch**
Number of Participants Analyzed **[units: participants]**	**273**	**273**
Change in Ten Point Clock Test (TPCT) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline **[units: Score on a scale]** **Mean (Standard Deviation)**		
Week 16	**0.5 (2.75)**	**0.4 (3.02)**
Week 24	**0.6 (3.18)**	**0.3 (3.40)**
Week 52	**0.3 (2.97)**	**-0.1 (3.33)**
Week 76	**0.0 (3.2)**	**-0.3 (3.57)**

No statistical analysis provided for Change in Ten Point Clock Test (TPCT) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline

6. Secondary: Change in Neuropsychiatric Inventory-10 (NPI-10) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline [Time Frame: At Week 16, 24, 52 and 76 (or early discontinuation)]

Measure Type	Secondary
Measure Title	Change in Neuropsychiatric Inventory-10 (NPI-10) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline
Measure Description	The parameter for analysis was the change from baseline of total score of 10 items on the NPI scale (NPI-10). The total score is a sum of the 10 domains, where the score for a domain is defined as the product of frequency (range: 1-4) and severity (range: 1-3). Each domain has a maximum score of 12 and all domains were equally weighted for total score(thus the range for the total score is 0 to 120 with 0 being completely healthy to 120 which is the worse score patient can get). The change from baseline was calculated such that a negative number indicates an improvement (symptom reduction).
Time Frame	At Week 16, 24, 52 and 76 (or early discontinuation)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population which included all patients who received at least 1 dose of study drug and had at least 1 pre- and post-baseline assessment for 1 of the efficacy variables. Last observation carried forward. (LOCF)

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	Rivastigmine Patch
Number of Participants Analyzed **[units: participants]**	**294**	**288**
Change in Neuropsychiatric Inventory-10 (NPI-10) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline **[units: Score]** **Mean (Standard Deviation)**		
Week 16	**-3.3 (9.75)**	**-0.5 (10.89)**
Week 24	**-2.6 (10.31)**	**-1.0 (10.27)**
Week 52	**-1.7 (11.40)**	**-0.3 (11.26)**
Week 76	**-1.6 (11.22)**	**0.7 (12.62)**

No statistical analysis provided for Change in Neuropsychiatric Inventory-10 (NPI-10) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline

7. Secondary: Change in Alzheimer's Disease Cooperative Study-Activities Of Daily Living (ADCS-ADL) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline [Time Frame: From Baseline to Week 16, 24, 52 and 76 (or early discontinuation)]

Measure Type	Secondary
Measure Title	Change in Alzheimer's Disease Cooperative Study-Activities Of Daily Living (ADCS-ADL) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline
Measure Description	The 23 item caregiver-based ADL scale of the dementia Alzheimer's disease Cooperative Study-Activities of Daily Living (ADCS-ADL) was used for analysis. This is a caregiver rated questionnaire of 23 items, with possible scores over a range of 0-78, where 78 denote full functioning with no impairment. The total score was derived by adding up the item scores of the 23 items. The change from baseline was calculated such that a positive change indicates an improvement.
Time Frame	From Baseline to Week 16, 24, 52 and 76 (or early discontinuation)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population which included all patients who received at least 1 dose of study drug and had at least 1 pre- and post-baseline assessment for 1 of the efficacy variables. Last observation carried forward. (LOCF).

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	**Rivastigmine Patch**
Number of Participants Analyzed **[units: participants]**	**294**	**288**
Change in Alzheimer's Disease Cooperative Study-Activities Of Daily Living (ADCS-ADL) Scores at Weeks 16, 24, 52 and 76 (or Early Discontinuation) Compared to Baseline **[units: Score]** **Mean (Standard Deviation)**		
Week 16 (n=273, 270)	**-0.4 (9.60)**	**-1.3 (10.38)**
Week 24 (n=273,270)	**-0.6 (10.12)**	**-1.5 (10.91)**
Week 52 (n=273,270)	**-2.2 (11.13)**	**-5.4 (13.57)**
Week 76 (n=273, 270)	**-4.4 (13.13)**	**-7.8 (15.62)**

No statistical analysis provided for Change in Alzheimer's Disease Cooperative Study-Activities Of Daily Living (ADCS-ADL) Scores at Weeks 16, 24, 52 and 76

(or Early Discontinuation) Compared to Baseline

8. Secondary: UPDRS Part V Stage (Modified Hoehn and Yahr Staging)at Baseline, Week 8,16,24,52 and 76 (or Early Discontinuation) [Time Frame: From Baseline to Week 8, 16, 24, 52 and 76 (or early discontinuation)]

Measure Type	Secondary
Measure Title	UPDRS Part V Stage (Modified Hoehn and Yahr Staging)at Baseline, Week 8,16,24,52 and 76 (or Early Discontinuation)
Measure Description	Unified Parkinson Disease Rating Scale (UPDRS) is a 6 part Parkinson's disease specific rating scale that estimates clinical function taking into consideration both disability (functional deficits) and impairment (objective clinical signs). UPDRS Part V is assessed by the modified Hoehn and Yahr Staging Scale. The scale ranges from 0 (no signs of disease) to 5 (wheelchair bound or bedridden unless aided).
Time Frame	From Baseline to Week 8, 16, 24, 52 and 76 (or early discontinuation)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Safety population consisted of all patients who have received at least one dose of study drug and have had at least 1 safety measurement after baseline. n=indicates patients with observation during different timepoints.

Reporting Groups

	Description
Rivastigmine Capsule	Rivastigmine capsules starting at a total dose of 3 mg/day (1.5 mg twice daily orally) titrated up in 3 mg/day increments every 4 weeks to a final dose of 12 mg/day (6 mg twice daily orally0. The 12 mg/day dose or the highest dose tolerated was maintained until week 76.
Rivastigmine Patch	Rivastigmine patch once a day in the morning, worn for 24 hours, starting at 5 cm^2 (delivering 4.6 mg rivastigmine over a 24 hour period) for 4 weeks then titrated up to 10 cm^2 daily (delivering 9.5 mg rivastigmine over a 24 hour period). The 10 cm^2 patch or the highest well tolerated dose was maintained until week 76.

Measured Values

	Rivastigmine Capsule	Rivastigmine Patch
Number of Participants Analyzed **[units: participants]**	**294**	**288**
UPDRS Part V Stage (Modified Hoehn and Yahr Staging)at Baseline, Week 8,16,24,52 and 76 (or Early Discontinuation) **[units: Score]** **Mean (Standard Deviation)**		
Baseline (n = 294,288)	**2.7 (0.65)**	**2.7 (0.70)**
Week 8 (n=17,18)	**2.6 (0.70)**	**2.7 (1.05)**
Week 16 (n=254,252)	**2.8 (0.68)**	**2.7 (0.67)**
Week 24 (229, 236)	**2.7 (0.75)**	**2.7 (0.67)**
Week 52 (n=202,208)	**2.8 (0.73)**	**2.8 (0.69)**
Week 76 (n=184, 175)	**2.8 (0.74)**	**2.8 (0.79)**

No statistical analysis provided for UPDRS Part V Stage (Modified Hoehn and Yahr Staging)at Baseline, Week 8,16,24,52 and 76 (or Early Discontinuation)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Exelon Capsule	Exelon Capsule
Exelon Patch	Exelon Patch

Serious Adverse Events

	Exelon Capsule	Exelon Patch
Total, serious adverse events		
# participants affected / at risk	87/294 (29.59%)	83/288 (28.82%)
Cardiac disorders		
Acute myocardial infarction †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Angina pectoris †1		
# participants affected / at risk	1/294 (0.34%)	2/288 (0.69%)
Arteriosclerosis coronary artery †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Atrial fibrillation †1		
# participants affected / at risk	3/294 (1.02%)	0/288 (0.00%)
Atrial flutter †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Atrioventricular block second degree †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Bradycardia †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Cardiac arrest †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Cardiac failure †1		
# participants affected / at risk	1/294 (0.34%)	2/288 (0.69%)
Cardiac failure acute †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Cardiac valve sclerosis †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)

Cardio-respiratory arrest [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Coronary artery disease [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Myocardial infarction [†1]		
# participants affected / at risk	**2/294 (0.68%)**	**2/288 (0.69%)**
Sinus arrhythmia [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Gastrointestinal disorders		
Abdominal distension [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Abdominal hernia [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Abdominal pain [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Abdominal pain upper [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Constipation [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Diarrhoea [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**3/288 (1.04%)**
Duodenal ulcer haemorrhage [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Gastric ulcer haemorrhage [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Haemorrhoidal haemorrhage [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Haemorrhoids [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**

Ileus †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Inguinal hernia †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Inguinal hernia strangulated †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Intestinal obstruction †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Melaena †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Mesenteric occlusion †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Nausea †1		
# participants affected / at risk	**2/294 (0.68%)**	**1/288 (0.35%)**
Pancreatitis †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Pancreatitis acute †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Periodontitis †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Rectal haemorrhage †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Salivary hypersecretion †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Small intestinal obstruction †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Umbilical hernia †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**

Vomiting †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
General disorders		
Asthenia †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Complication of device insertion †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Device failure †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Fatigue †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Gait disturbance †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
General physical health deterioration †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Non-cardiac chest pain †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Pyrexia †1		
# participants affected / at risk	**2/294 (0.68%)**	**3/288 (1.04%)**
Hepatobiliary disorders		
Cholelithiasis †1		
# participants affected / at risk	**2/294 (0.68%)**	**1/288 (0.35%)**
Infections and infestations		
Bronchitis †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Bronchopneumonia †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Cellulitis †1		

# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Cystitis klebsiella †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Gastroenteritis viral †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Gastrointestinal infection †1		
# participants affected / at risk	2/294 (0.68%)	0/288 (0.00%)
Helicobacter infection †1		
# participants affected / at risk	2/294 (0.68%)	0/288 (0.00%)
Lung infection †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Pneumonia †1		
# participants affected / at risk	9/294 (3.06%)	7/288 (2.43%)
Pneumonia fungal †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Post procedural sepsis †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Rash pustular †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Respiratory tract infection †1		
# participants affected / at risk	2/294 (0.68%)	0/288 (0.00%)
Sepsis †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Tracheobronchitis †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Urinary tract infection †1		
# participants affected / at risk	2/294 (0.68%)	4/288 (1.39%)
Injury, poisoning and procedural complications		

Accidental overdose †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Brain herniation †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Concussion †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Contusion †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Fall †1		
# participants affected / at risk	**2/294 (0.68%)**	**9/288 (3.13%)**
Femoral neck fracture †1		
# participants affected / at risk	**2/294 (0.68%)**	**1/288 (0.35%)**
Femur fracture †1		
# participants affected / at risk	**6/294 (2.04%)**	**3/288 (1.04%)**
Hand fracture †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Head injury †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Hip fracture †1		
# participants affected / at risk	**3/294 (1.02%)**	**2/288 (0.69%)**
Humerus fracture †1		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Lower limb fracture †1		
# participants affected / at risk	**1/294 (0.34%)**	**2/288 (0.69%)**
Nerve root injury †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Pelvic fracture †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Post-traumatic pain †1		

# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Rib fracture †1		
# participants affected / at risk	1/294 (0.34%)	2/288 (0.69%)
Scapula fracture †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Skin laceration †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Spinal compression fracture †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Spinal fracture †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Upper limb fracture †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Wrist fracture †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Investigations		
Weight decreased †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Metabolism and nutrition disorders		
Decreased appetite †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Dehydration †1		
# participants affected / at risk	3/294 (1.02%)	4/288 (1.39%)
Hypokalaemia †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Weight loss poor †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Musculoskeletal and connective tissue disorders		

Arthralgia †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Back pain †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**
Bursitis †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Mobility decreased †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Musculoskeletal discomfort †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Pathological fracture †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Spinal osteoarthritis †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Synovitis †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Bladder cancer †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Breast cancer †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Malignant melanoma †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Meningioma benign †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Prostate cancer †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Rectosigmoid cancer †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**

Waldenstrom's macroglobulinaemia †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Nervous system disorders		
Akinesia †1		
# participants affected / at risk	**2/294 (0.68%)**	**3/288 (1.04%)**
Aphasia †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Balance disorder †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Basilar artery thrombosis †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Bradykinesia †1		
# participants affected / at risk	**2/294 (0.68%)**	**3/288 (1.04%)**
Cerebral infarction †1		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Cerebrovascular accident †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Cognitive disorder †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Cogwheel rigidity †1		
# participants affected / at risk	**4/294 (1.36%)**	**2/288 (0.69%)**
Coma †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Convulsion †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Dementia †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Depressed level of consciousness †1		

# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Dizziness †1		
# participants affected / at risk	**1/294 (0.34%)**	**3/288 (1.04%)**
Dysarthria †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Dyskinesia †1		
# participants affected / at risk	**0/294 (0.00%)**	**3/288 (1.04%)**
Epilepsy †1		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Freezing phenomenon †1		
# participants affected / at risk	**2/294 (0.68%)**	**1/288 (0.35%)**
Hypokinesia †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Lacunar infarction †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Loss of consciousness †1		
# participants affected / at risk	**1/294 (0.34%)**	**2/288 (0.69%)**
Monoparesis †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
On and off phenomenon †1		
# participants affected / at risk	**3/294 (1.02%)**	**0/288 (0.00%)**
Parkinson's disease †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Parkinsonian gait †1		
# participants affected / at risk	**3/294 (1.02%)**	**2/288 (0.69%)**
Parkinsonian rest tremor †1		
# participants affected / at risk	**3/294 (1.02%)**	**2/288 (0.69%)**
Psychomotor hyperactivity †1		
# participants affected / at risk	**2/294 (0.68%)**	**0/288 (0.00%)**

Psychomotor skills impaired [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Quadriplegia [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Somnolence [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Syncope [†1]		
# participants affected / at risk	**5/294 (1.70%)**	**1/288 (0.35%)**
Transient ischaemic attack [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**4/288 (1.39%)**
Psychiatric disorders		
Agitation [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Anxiety [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Confusional state [†1]		
# participants affected / at risk	**3/294 (1.02%)**	**6/288 (2.08%)**
Delirium [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Delusion [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Depression [†1]		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Hallucination [†1]		
# participants affected / at risk	**1/294 (0.34%)**	**4/288 (1.39%)**
Hallucination, visual [†1]		
# participants affected / at risk	**3/294 (1.02%)**	**3/288 (1.04%)**
Insomnia [†1]		

# participants affected / at risk	0/294 (0.00%)	2/288 (0.69%)
Mental status changes [†1]		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Psychotic disorder [†1]		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Psychotic disorder due to a general medical condition [†1]		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Renal and urinary disorders		
Bladder trabeculation [†1]		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Calculus bladder [†1]		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Haematuria [†1]		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Micturition urgency [†1]		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Renal failure [†1]		
# participants affected / at risk	1/294 (0.34%)	1/288 (0.35%)
Urinary bladder polyp [†1]		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Urinary incontinence [†1]		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Urinary retention [†1]		
# participants affected / at risk	2/294 (0.68%)	0/288 (0.00%)
Urinary tract obstruction [†1]		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Reproductive system and breast disorders		
Benign prostatic hyperplasia [†1]		

# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Prostatic obstruction †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Respiratory, thoracic and mediastinal disorders		
Acute pulmonary oedema †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Brain hypoxia †1		
# participants affected / at risk	1/294 (0.34%)	1/288 (0.35%)
Dyspnoea †1		
# participants affected / at risk	3/294 (1.02%)	1/288 (0.35%)
Lung disorder †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Pleural effusion †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Pneumonia aspiration †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Productive cough †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Pulmonary embolism †1		
# participants affected / at risk	4/294 (1.36%)	1/288 (0.35%)
Pulmonary oedema †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Respiratory arrest †1		
# participants affected / at risk	1/294 (0.34%)	0/288 (0.00%)
Skin and subcutaneous tissue disorders		
Skin ulcer †1		
# participants affected / at risk	0/294 (0.00%)	1/288 (0.35%)
Urticaria †1		

# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Vascular disorders		
Haematoma †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Hypertension †1		
# participants affected / at risk	**0/294 (0.00%)**	**2/288 (0.69%)**
Hypertensive crisis †1		
# participants affected / at risk	**1/294 (0.34%)**	**1/288 (0.35%)**
Hypotension †1		
# participants affected / at risk	**3/294 (1.02%)**	**0/288 (0.00%)**
Orthostatic hypotension †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**
Peripheral arterial occlusive disease †1		
# participants affected / at risk	**0/294 (0.00%)**	**1/288 (0.35%)**
Phlebitis †1		
# participants affected / at risk	**1/294 (0.34%)**	**0/288 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Exelon Capsule	Exelon Capsule
Exelon Patch	Exelon Patch

Other Adverse Events

	Exelon Capsule	Exelon Patch
Total, other (not including serious) adverse events		
# participants affected / at risk	**239/294 (81.29%)**	**215/288 (74.65%)**
Gastrointestinal disorders		
Constipation †1		
# participants affected / at risk	**21/294 (7.14%)**	**21/288 (7.29%)**
Diarrhoea †1		
# participants affected / at risk	**27/294 (9.18%)**	**14/288 (4.86%)**
Nausea †1		
# participants affected / at risk	**117/294 (39.80%)**	**23/288 (7.99%)**
Vomiting †1		
# participants affected / at risk	**45/294 (15.31%)**	**7/288 (2.43%)**
General disorders		
Application site erythema †1		
# participants affected / at risk	**0/294 (0.00%)**	**40/288 (13.89%)**
Fatigue †1		
# participants affected / at risk	**19/294 (6.46%)**	**13/288 (4.51%)**
Infections and infestations		
Urinary tract infection †1		
# participants affected / at risk	**17/294 (5.78%)**	**21/288 (7.29%)**
Injury, poisoning and procedural complications		

Fall [†1]		
# participants affected / at risk	**48/294 (16.33%)**	**49/288 (17.01%)**
Investigations		
Weight decreased [†1]		
# participants affected / at risk	**19/294 (6.46%)**	**18/288 (6.25%)**
Metabolism and nutrition disorders		
Decreased appetite [†1]		
# participants affected / at risk	**18/294 (6.12%)**	**12/288 (4.17%)**
Musculoskeletal and connective tissue disorders		
Back pain [†1]		
# participants affected / at risk	**13/294 (4.42%)**	**16/288 (5.56%)**
Nervous system disorders		
Bradykinesia [†1]		
# participants affected / at risk	**13/294 (4.42%)**	**15/288 (5.21%)**
Dizziness [†1]		
# participants affected / at risk	**26/294 (8.84%)**	**21/288 (7.29%)**
Headache [†1]		
# participants affected / at risk	**15/294 (5.10%)**	**12/288 (4.17%)**
On and off phenomenon [†1]		
# participants affected / at risk	**12/294 (4.08%)**	**16/288 (5.56%)**
Parkinsonian gait [†1]		
# participants affected / at risk	**15/294 (5.10%)**	**12/288 (4.17%)**
Parkinsonian rest tremor [†1]		
# participants affected / at risk	**69/294 (23.47%)**	**26/288 (9.03%)**
Somnolence [†1]		
# participants affected / at risk	**23/294 (7.82%)**	**18/288 (6.25%)**
Psychiatric disorders		
Anxiety [†1]		

# participants affected / at risk	**17/294 (5.78%)**	**22/288 (7.64%)**
Confusional state †1		
# participants affected / at risk	**21/294 (7.14%)**	**21/288 (7.29%)**
Depression †1		
# participants affected / at risk	**6/294 (2.04%)**	**22/288 (7.64%)**
Hallucination †1		
# participants affected / at risk	**19/294 (6.46%)**	**21/288 (7.29%)**
Hallucination, visual †1		
# participants affected / at risk	**12/294 (4.08%)**	**16/288 (5.56%)**
Insomnia †1		
# participants affected / at risk	**14/294 (4.76%)**	**23/288 (7.99%)**
Vascular disorders		
Hypertension †1		
# participants affected / at risk	**16/294 (5.44%)**	**12/288 (4.17%)**
Hypotension †1		
# participants affected / at risk	**22/294 (7.48%)**	**10/288 (3.47%)**
Orthostatic hypotension †1		
# participants affected / at risk	**18/294 (6.12%)**	**17/288 (5.90%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

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No publications provided

Responsible Party: Novartis
ClinicalTrials.gov Identifier: NCT00623103 History of Changes
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