

# A drug utilisation study in patients treated with EXELON®/PROMETAX® (rivastigmine) transdermal patch

**First published:** 24/09/2014

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/27280>

### EU PAS number

EUPAS7537

### Study ID

27280

### DARWIN EU® study

No

### Study countries

☐ Germany

- ☐ Greece
  - ☐ Portugal
  - ☐ United Kingdom
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### Study description

Exelon/Prometax is indicated for mild to moderately severe Alzheimer's dementia. Postmarketing adverse event reports have documented instances of medication misuse and medication error. EMA/CHMP requested development of educational materials to help minimise multiple patch use. The aim of this DUS is to assess the extent of inappropriate use of Exelon/Prometax patches following introduction of this new educational materials and to assess titration patterns. This proposed DUS is a prospective, non-interventional, multinational, multicentre, cohort field post-authorization safety study (PASS) of physician prescribing patterns and patient use of Exelon/Prometax patches. The study will be implemented in EU, e.g., Germany, Greece, Portugal, United Kingdom. The total study population is ~800 patients. Total duration of patient data collection will be up to 11 months for each patient.

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### Study status

Finalised

## Research institutions and networks

### Institutions

**Novartis Pharmaceuticals**

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## Multiple centres

Multiple centres: 80 centres are involved in the study

## Contact details

### Study institution contact

Novartis Clinical Disclosure Officer

Study contact

[Trialandresults.registries@novartis.com](mailto:Trialandresults.registries@novartis.com)

### Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 14/05/2013

Actual: 14/05/2013

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**Study start date**

Planned: 17/11/2014

Actual: 12/11/2014

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**Data analysis start date**

Planned: 17/11/2015

Actual: 17/11/2015

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**Date of final study report**

Planned: 13/12/2018

Actual: 14/11/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novartis

## Study protocol

[cena713d2409-redacted protocol.pdf](#)(756.01 KB)

[ena713d2409-v02--protocol amendment redacted.pdf](#)(1.06 MB)

## Regulatory

**Was the study required by a regulatory body?**

No

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

## Other study registration identification numbers and links

CENA713D2409

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

#### **Data collection methods:**

Primary data collection

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#### **Main study objective:**

To assess appropriate use and estimate amount and type of inappropriate drug use of all doses of Exelon/Prometax patches as recorded by patients and/or their assistants Estimation of inappropriate use will be stratified by characteristics of patients, patient assistants, and physicians, if possible To assess titration patterns of Exelon/Promet

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medical condition to be studied**

Dementia Alzheimer's type

## Population studied

### **Short description of the study population**

Physician prescribing patterns and patient use of Exelon/Prometax patches

To be eligible for the study, patients were required to meet all of the following criteria:

1. Currently using Exelon/Prometax patch (i.e., 4.6 mg/24 hour [5 cm<sup>2</sup>], 9.5 mg/24 hour [10 cm<sup>2</sup>], or 13.3 mg/24 hour [15 cm<sup>2</sup>]) or where an independent decision has been made by their health care professional to initiate treatment with Exelon/Prometax patch at baseline. In Germany (as requested by BfArM) the following will also apply: Exelon/Prometax patch treatment to be in

accordance with the approved SmPC.

2. Have an assistant who is willing to participate in the study and is able to understand and comply with study procedures in the local language and able to provide informed consent for themselves. The patient assistant does not need to be a primary or formal caregiver and can include a family member or other individual who helps with the patient's activities of daily living.
  3. Able to provide informed consent to participate in the study or have a legal representative who is willing and able to provide informed consent on their behalf.
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### **Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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### **Estimated number of subjects**

600

## **Study design details**

### **Outcomes**

The outcomes of interest include inappropriate use, titration patterns, and perceived usefulness of the Exelon/Prometax patch Patient Reminder Card (e.g. the new educational material).

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### **Data analysis plan**

The main analysis will estimate (with 95% confidence intervals) the percentage of patients with inappropriate use and the percentage of days with

inappropriate use. Results will be presented both for overall/any inappropriate use as well as by type of inappropriate use (e.g. multiple patches, incorrect anatomical skin site). Results will be stratified by country and other logical variables, such as patient age, severity of dementia, time since diagnosis of dementia, previous patch use, completeness of the Medication Record Sheets, and practice/physician characteristics, where possible. Titration will be described by summarising the time elapsed from lower to higher dose and by describing the main indications for dose change. Elapsed time, as summary measures or distributions, will be presented separately for each type of dose change (e.g. oral to patch, each patch dose to next higher dose, change from higher dose to lower dose).

## Documents

### Study results

[ena713d2409--legacy-clinical-study-report\\_Redacted2.pdf](#)(6.45 MB)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)



## CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No