

# SHP617-404: A SWEDISH RETROSPECTIVE STUDY EVALUATING THE PATTERN OF PLENADREN USE FROM SWEDISH QUALITY REGISTRIES (SWE-DUS)

**First published:** 18/05/2016

**Last updated:** 31/03/2022

Study

Finalised

## Administrative details

### EU PAS number

EUPAS13232

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### Study ID

46491

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### DARWIN EU® study

No

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### Study countries

Sweden

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### Study description

THE STUDY DID NEVER START AND NO PATIENTS WERE ENROLLED. This is an open-ended, non-interventional, retrospective, drug utilization study which will assess data extracted from the Swedish National Quality Register regarding drug prescribing patterns, including any off-label use of PLENADREN. Data will be obtained from 2 registries within the Swedish National Quality Register, the National Patient Register (NPR, includes both inpatient and outpatient information) and the National Pharmaceutical Drug Register (NPDR). Data will be extracted from the registries after the launch of PLENADREN in Sweden (01 November 2012) and as soon as the number of patients treated with PLENADREN is estimated to be sufficient to perform an analysis, and will continue once yearly until the study is discontinued. PLENADREN is reported to be used off-label in adults for the treatment of the condition “adrenal fatigue”, which is not a medically distinct syndrome.

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### Study status

Finalised

## Research institutions and networks

### Institutions

Shire

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Institution

### Contact details

### **Study institution contact**

Call Center Shire [ClinicalTransparency@shire.com](mailto:ClinicalTransparency@shire.com)

**Study contact**

[ClinicalTransparency@shire.com](mailto:ClinicalTransparency@shire.com)

### **Primary lead investigator**

Call Center Shire

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 20/11/2013

Actual: 20/11/2013

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### **Study start date**

Planned: 20/11/2013

Actual: 20/11/2013

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### **Date of final study report**

Planned: 20/11/2013

Actual: 20/11/2013

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Shire

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Human medicinal product

Disease /health condition

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#### **Study type:**

Non-interventional study

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

Drug utilisation

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The main objective of this study is to monitor any off-label use of PLENADREN.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Open-ended, non-interventional, retrospective study, prescription event monitoring, case-series

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

HYDROCORTISONE

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**Medical condition to be studied**

Adrenal insufficiency

## Population studied

**Short description of the study population**

Patients treated with PLENADREN.

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## **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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**

20

## **Study design details**

### **Outcomes**

Percentage of patients prescribed PLENADREN who are <18 years of age, and Percentage of patients receiving PLENADREN for reasons other than treatment of AI (Adrenal insufficiency), Assessment of physician prescribing patterns for PLENADREN.

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### **Data analysis plan**

A summary of the data incorporated in the analysis reports will be included in the annual Period Benefit-Risk Evaluation Report (PBRER) for PLENADREN. All continuous variables will be summarized using standard statistical measures (i.e number of observations, mean, standard deviation SD, median, minimum, and maximum). All categorical variables will be summarized in frequency

tables. Demographic and baseline data, as well as disease and treatment characteristics data, will be summarized using descriptive statistics. The primary and secondary endpoints of the study will be presented descriptively and summarized using 95% CIs. Subgroup data will also be presented descriptively.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Disease registry](#)

[Drug registry](#)

[Other](#)

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### Data sources (types), other

Prescription event monitoring

## 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