# Post-authorisation safety study of NOCDURNA for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria: A multi-country cohort study using secondary data. (NOCDURNA PASS)

**First published:** 07/01/2021

**Last updated:** 06/11/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS38365

**Study ID**

48154

**DARWIN EU® study**

No

**Study countries**

- ☐ Denmark
- ☐ Germany

Sweden

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Ferring Pharmaceuticals

**First published:** 01/02/2024

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**Institution**

## Contact details

**Study institution contact**

Christian Froesig Disclosure@ferring.com

**Study contact**

Disclosure@ferring.com

**Primary lead investigator**

Christian Froesig

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 30/11/2020

**Study start date**
Planned: 01/07/2021

Actual: 01/07/2021

**Data analysis start date**
Planned: 01/08/2021

Actual: 01/07/2021

**Date of interim report, if expected**
Planned: 31/12/2021

**Date of final study report**
Planned: 11/12/2023

Actual: 30/01/2024

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Ferring Pharmaceuticals

## Study protocol

000248_CoverPage_Protocol_SAP_30Oct2024_PDFA.pdf (1.95 MB)

## Regulatory

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

Yes

**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

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

**Main study objective:**

Retrospective study to assess the post-authorisation safety of NOCDURNA using longitudinal RWD. Also, since it is desirable to put these observations into context and characterise a population with similar indications who do not

receive desmopressin, a similar number of patients receiving standard care for other lower urinary tract symptoms will be evaluated in order to inform NOCDUR safety and use.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

DESMOPRESSIN

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**Anatomical Therapeutic Chemical (ATC) code**

(H01BA02) desmopressin

desmopressin

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**Medical condition to be studied**

Nocturia

## Population studied

**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**

7090

# Study design details

**Outcomes**

To estimate the incidence rate of symptomatic hyponatraemia (defined as a recorded diagnosis of hyponatraemia) among patients treated with NOCDURNA, and patients with LUTS separately, overall and by subgroups of interest (including elderly patients, aged ≥ 65years). 1. Describe the demographic 2. Incidence rate of hyponatraemia requiring hospital intensive care 3. Incidence rate of hyponatraemia 4. Rate of mortality 5. Incidence rate of CV and venous thromboembolic events 6. Incidence rate of acute exacerbation of CHF 7. Patients adhering to the label 8. Adjustment for confounding 9. Treatment withdrawal of NOCDURNA

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**Data analysis plan**

This is a multi-country, cohort study using secondary data collected from research databasesand administrative national healthcare registries in selected European countries (Denmark, Germany and Sweden). Cohorts of patients using NOCDURNA or treatment of LUTS (new user) will be identified from existing data sources in each country of study. These data sources hold information on dispensed prescriptions, patient demographics and diagnoses. The LUTS contextual cohort will be comprised of patients based newly starting treatments associated with polyuria, receiving relevant standard care. For secondary comparative analyses, the comparator group for NOCDURNA patients will be

LUTS patients. In addition to the final study report, there will be annual interim reports on study progress and any emerging safety data. Both country-specific and pooled results (meta-analysis) will be presented in the final report, where data are available.

## Documents

**Study report**

000248_Report_Synopsis_30Oct2024_PDFA.pdf (284.9 KB)

# 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 source(s)**

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

German Pharmacoepidemiological Research Database

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**Data sources (types)**

Drug dispensing/prescription data

## Use of a Common Data Model (CDM)

**CDM mapping**

No

# Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

No