Incidence of tolerance, dependence, drug abuse and misuse of Targin in patients with Restless Legs Syndrome

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Study Finalised

Administrative details

EU PAS number

EUPAS41097

Study ID

41661

DARWIN EU® study

No

Study countries

☐ Germany

Study status

Finalised

Research institutions and networks

Institutions

Institute for Applied Health Research Berlin (InGef)

Germany

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Institution | Educational Institution

Contact details

Study institution contact

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Primary lead investigator

Lee Seuunghee

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/02/2018

Actual: 28/02/2018

Study start date
Planned: 01/10/2020

Actual: 01/10/2020

Date of final study report
Planned: 29/03/2021

Actual: 29/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Mundipharma

Regulatory

Was the study required by a regulatory body?

Unknown

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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:

To estimate the incidence of problematic Targin prescription use and abuse in patients treated with Targin for RLS.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Name of medicine, other

Targin

Medical condition to be studied

Restless legs syndrome

Population studied

Short description of the study population

Patients with Restless Legs Syndrome.

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)

Estimated number of subjects

2757

Study design details

Outcomes

confirmed problematic Targin use had a low incidence rate and high doses and long prescribing were also reasonably uncommon while there was a moderate proportion of patients using other opioids during Targin exposure. While confirmed opioid abuse/dependency may be underreported in a routine

healthcare database such as InGef, not all of the identified occurrences may be attributed to Targin. To characterise Targin for RLS treatment patterns in patients To estimate the incidence of “suspected doctor shopping” in patients treated with Targin for RLS To estimate the amount of off-label use of Targin in RLS patients To determine concomittant treatment in patients treated with Targin for RLS. To estimate incidences of pre-specified adverse events during treatment

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Data analysis plan

Statistical analysis were carried out using the data environment used by InGef.

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)

Drug registry

Other

Data sources (types), other

Prescription event monitoring

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