# Evaluation of the safety profile of lurasidone: a post-authorization safety study using United States administrative claims databases (Lurasidone PASS program)

**First published:** 05/03/2020

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Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/40822

**EU PAS number**

EUPAS34004

**Study ID**

40822

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The aim of this PASS study is to evaluate the safety profile of lurasidone for treatment of schizophrenia in a real-world setting. The primary objective is to compare the incidence of important identified risks and important potential risks in patients treated with lurasidone to patients treated with other second generation oral atypical antipsychotics (OAAs).

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Angelini Pharma

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

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Institution

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Fabrizio Calisti

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 13/12/2019

**Study start date**
Actual: 05/03/2020

**Date of final study report**
Planned: 30/12/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Angelini Pharma SpA

## 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)

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Main study objective:**

The primary objective is to compare the incidence of important identified risks and important potential risks in patients treated with lurasidone to patients treated with other second generation oral atypical antipsychotics (OAAs).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Name of medicine**

LATUDA

**Medical condition to be studied**

Schizophrenia

## Population studied

**Age groups**

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)

**Estimated number of subjects**

6611

## Study design details

**Outcomes**

The primary outcomes include important risks to patients receiving OAAs, and those risks can be regarded as identified or potential

**Data analysis plan**

The primary analyses will include:• Patient attrition• Descriptive statistics on the demographics and clinical characteristics of the two study cohorts • The number and percent of patients exposed to lurasidone and other OAAs• The

number and percent of patients experiencing the outcomes of interest among the two study cohortsAnalyses will be conducted overall and for the subgroups specified.

# Data management

## 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