# An Observational Drug Utilization Study of SYCREST® (asenapine) in the United Kingdom (P08308)

**First published:** 31/05/2017

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

Study Finalised

## Administrative details

**EU PAS number**

EUPAS17681

**Study ID**

24560

**DARWIN EU® study**

No

**Study countries**

United Kingdom

**Study description**

This is a retrospective observational cohort study designed to describe asenapine prescribing patterns in the United Kingdom (UK) during the post-approval period in the general practice (GP) setting. The use of asenapine in Bipolar Disorder (BD) and other indications including Schizophrenia will be described. To provide epidemiological and clinical perspective, use of aripiprazole, olanzapine, quetiapine, and risperidone will also be described.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Merck Sharp & Dohme LLC

United States

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

**Last updated:** 08/07/2025

Institution | Pharmaceutical company

# Contact details

**Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
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Study contact

datasharing@organon.com

**Primary lead investigator**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 02/12/2010

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**Study start date**

Actual: 01/04/2013

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**Data analysis start date**

Planned: 18/12/2017

Actual: 21/12/2017

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**Date of interim report, if expected**

Actual: 13/09/2013

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**Date of final study report**

Planned: 31/01/2018

Actual: 25/01/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Merck Sharp & Dohme Corp

## Study protocol

8274-108+Protocol+AM3_final-redaction.pdf (304.77 KB)

## 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)

## Other study registration identification numbers and links

NCT01498770SCH 900274 P08308MK-8274-108

# 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:**

Secondary use of data

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**Main study objective:**

1. Describe baseline demographic characteristics, clinical characteristics and healthcare utilization among new users of asenapine aged 18+ years 2. Identify and describe a recent-historical, matched aripiprazole cohort in general practice among patients aged 18+ years, to put asenapine use into context3. Describe off-label use of asenapine in general practice among patients aged 0-17 years

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

SYCREST

**Medical condition to be studied**

Bipolar disorder

Schizophrenia

# Population studied

**Short description of the study population**

Patients prescribed asenapine or any other comparator (olanzapine, quetiapine, ziprasidone, iloperidone, risperidone, paliperidone, lurasidone, clozapine, amisulpride, sertindole, zotepine or aripiprazole) as recorded in CPRD UK and meet following criteria-

1) >1 prescription for asenapine or any comparator within the study period

2) Age 18+ at the time the patient receives a prescription for the comparator

3) Date of prescription for asenapine or any comparator occurs after the patient registration date or the database specific quality indicator date

4) A minimum of >365 days of evaluable baseline observation time, occurring prior to the date of prescription for asenapine or any comparator.

**Age groups**

- 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)

**Special population of interest**

Other

**Special population of interest, other**

Patients with schizophrenia, bipolar disorder or any other psychotic disorder

**Estimated number of subjects**

3.000

## Study design details

**Outcomes**

1. Frequency and proportion of use, by psychiatric diagnosis, among new users of asenapine and aripiprazole aged 18+ years in the CPRD and THIN databases2. Frequency and proportion of pediatric use, by psychiatric diagnosis, among asenapine users in the CPRD and THIN databases3. Demographic, clinical characteristics and healthcare utilization among new users of asenapine and aripiprazole

**Data analysis plan**

All analyses for this drug utilization study will be descriptive. No statistical hypothesis testing will be conducted in this observational study. The frequency and proportions of on- and off-label use will be described.An epidemiology Safety Review Committee comprised of independent clinicians and experts will perform integrated review of the findings of the study, and evaluate the safety data that emerge from the study using both clinical judgment and pre-specified statistical criteria as guidelines.

## Documents

**Study results**

MK-8274-108_final-report_NoAppendices_final-redaction.pdf (2.2 MB)

# 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)**

THIN® (The Health Improvement Network®)

Clinical Practice Research Datalink

**Data sources (types)**

Electronic healthcare records (EHR)

## 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**

Unknown