A Retrospective and prospective, obsErvational (non-interventional), post-authorization Safety cohort sTudy to evaluate the incidence of the breAkages and insertion/Removal complications of buprenorphine implants in rouTine clinical care (RE-START)

First published: 19/04/2024

Last updated: 09/02/2026

Study Discontinued

Administrative details

EU PAS number

EUPAS1000000092

Study ID

1000000092

DARWIN EU® study

No

Study countries

Italy

Study description

RE-START study, under real world conditions, aims to describe the rate of breakage of Sixmo® implants occurring during the observation period. The study population consists of adult patients with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

Study status

Discontinued

Research institutions and networks

Institutions

L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

Contact details

Study institution contact

RE-START study Team RE-START@moltenifarma.it

Study contact

RE-START@moltenifarma.it

Primary lead investigator

Claudio Leonardi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/05/2024

Study start date

Actual: 10/06/2024

Date of final study report

Planned: 31/12/2026

Actual: 30/01/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

The Sponsor of RE-START study is L. Molteni & C. dei Fratelli Alitti Società di Esercizio S.p.A.

(Address: Strada Statale 67 - Loc. Granatieri 50018 Scandicci (Fi), Italy)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Regulatory procedure number

EMEA/H/C/PSA/S/0097

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Study design:

Multi-centre, retrospective and prospective cohort, observational (non-interventional) PASS

Main study objective:

The primary objective is:

- To describe the rate of breakage of Sixmo® implants (endpoint: all implant breakages reported as occurring during the treatment period, whether or not associated with adverse events linked to Sixmo® implant).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SIXMO

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

BUPRENORPHINE

Anatomical Therapeutic Chemical (ATC) code

(N07BC01) buprenorphine

buprenorphine

Additional medical condition(s)

Opioid dependence

Population studied

Short description of the study population

Study population will consist of alive male and female patients aged 18 years or over, with a diagnosis of opioid dependence and treated with Sixmo® as part of their routine clinical care, according to the approved Summary of Product Characteristics (SmPC).

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

120

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.

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