An observational study on 75 mg Tramadol/25 mg Dexketoprofen fixed-dose combination in the treatment of post-surgical pain in patients undergoing day surgery (SERENITY)

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Study Planned

Administrative details

EU PAS number

EUPAS1000000216

Study ID

1000000216

DARWIN EU® study

No

Study countries

☐ Poland

Study description

Non-interventional, prospective, uncontrolled, and multicentre. The study will include 200 patients. Assuming approximately a 15% drop-out rate, 170 patients are expected to be evaluable. The study population will comprise adult patients (male and female, aged 18 years or older) undergoing day surgeries and managed as outpatients following hospital discharge.

Study status

Planned

Research institutions and networks

Institutions

A. Menarini Farmaceutica Internazionale S.r.l.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 01/08/2024

Study start date
Planned: 22/12/2024

Date of final study report
Planned: 22/06/2026

Sources of funding

- Pharmaceutical company and other private sector

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02AJ14) tramadol and dexketoprofen

tramadol and dexketoprofen

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 The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.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