

# Evaluation of the Use of Nepafenac in Selected European Populations

**First published:** 27/11/2013

**Last updated:** 13/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5278

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### Study ID

20038

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### DARWIN EU® study

No

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### Study countries

 Denmark

 Netherlands

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### Study description

This study is a drug utilization study to evaluate the use of nepafenac (Nevanac), an ophthalmic non-steroidal agent, in two selected European

populations from Denmark and The Netherlands. In Europe, nepafenac has been approved for (1) prevention and treatment of postoperative pain and inflammation associated with cataract surgery in adults (approval in 2007) and (2) to reduce the risk of macular edema after cataract surgery in diabetic patients (approval in 2011). The aim of this study is describe the use of nepafenac. This will be a cohort study including new users of nepafenac and new users of other selected ophthalmic NSAIDs. The study will be conducted in the network of databases from the National Health Databases in Denmark and the PHARMO Record Linkage System database in the Netherlands. Patients will become eligible for cohort entry after 6 months of enrolment in the databases. The exposure will be based on dispensed prescriptions, medical condition concomitant to the exposure will be derived from diagnoses and procedures around the prescription dispensing date. Target conditions for this evaluation are cataract surgery, refractive procedures, other ophthalmic procedures, two or more ophthalmic surgeries or procedures, dry eye/Sjögren syndrome, uveitis/iritis, ophthalmic manifestations of allergy, ocular pain, macular edema, vitreous-related disorders. The study will report the frequency of the demographic characteristics of nepafenac users and users of other selected individual ophthalmic NSAIDs. The potential off-label use of nepafenac will be characterized as, a) use not preceded by cataract surgery b) use preceded by cataract but longer than 21 days in patients without diabetes or longer than 60 days in patients with diabetes c) use in individuals aged less than 19 years.

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## **Study status**

Finalised


## **Research institutions and networks**


### **Institutions**


## RTI Health Solutions (RTI-HS)


 France

 Spain

 Sweden

 United Kingdom

 United Kingdom (Northern Ireland)

 United States

**First published:** 21/04/2010

**Last updated:** 13/03/2025


**Institution**

**Not-for-profit**

**ENCePP partner**

N/A

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022


**Last updated:** 19/12/2025

**Institution**


**Non-Pharmaceutical company**


**ENCePP partner**


RTI Health Solutions (RTI-HS)


 France

 Spain

 Sweden

 United Kingdom

 United Kingdom (Northern Ireland)

 United States

**First published:** 21/04/2010


**Last updated:** 13/03/2025

**Institution**

**Not-for-profit**

**ENCePP partner**

## Pharmacoepi center, University of Southern Denmark

 Denmark

**First published:** 22/04/2010

**Last updated:** 27/07/2023

**Institution**

**Educational Institution**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[aarana@rti.org](mailto:aarana@rti.org)

## Primary lead investigator

Alejandro Arana Navarro

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/02/2013

Actual: 25/03/2013

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### Study start date

Planned: 30/06/2015

Actual: 22/09/2015

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### Data analysis start date

Planned: 01/08/2015

Actual: 22/09/2015

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### Date of final study report

Planned: 31/03/2016

Actual: 31/03/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Alcon Labs, Inc.

# Study protocol

[Redacted Nevanac Protocol Summary.pdf](#) (584.01 KB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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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 topic:**

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:**

The main objective of the study is to characterize off-label use of nepafenac.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(S01BC10) nepafenac

nepafenac

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**Medical condition to be studied**

Off label use

## Population studied

**Short description of the study population**

New users of nepafenac and new users of other selected ophthalmic NSAIDs with at least 6 months of previous enrolment in the database.

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**Age groups**

- Adolescents (12 to < 18 years)

- Children (2 to < 12 years)
  - Infants and toddlers (28 days - 23 months)
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - 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)
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### **Estimated number of subjects**

4000

## Study design details

### **Data analysis plan**

The analysis will be descriptive. In the baseline analysis, characteristics of users of nepafenac and users of other selected ophthalmic NSAIDs will be assessed at the cohort entry date. The medical condition associated with use of nepafenac and other ophthalmic NSAIDs will be also assessed. In the treatment period analysis, a) patterns of duration of prescriptions for nepafenac or other ophthalmic NSAIDs will be evaluated, especially those of off-label duration b) patterns of duration of prescriptions for nepafenac or other ophthalmic NSAIDs without prior cataract surgery will be evaluated c) the proportion of patients using specific medications during treatment with nepafenac or other ophthalmic NSAIDs will be evaluated.

## Documents

## Study publications

Margulis AV, Houben E, Hallas J, Overbeek JA, PottegAard A, Torp-Pedersen T, Pe...

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## 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)

NO LONGER EXISTS - Odense Pharmacoepidemiological Database  
PHARMO Data Network

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### Data sources (types)

[Disease registry](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No