

# A non-interventional, population-based register study on the prescription of etoricoxib (Arcoxia®) to dental surgery patients in the Nordic countries (MK-0663-170)

**First published:** 15/08/2014

**Last updated:** 11/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7134

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### Study ID

25929


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### DARWIN EU® study


No

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### Study countries

 Denmark

 Finland

 Norway

 Sweden

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## Study description

The objectives of this study are to: 1) describe dispensed etoricoxib prescribed by dentists including the associated dental procedures, patient demographics, dosing, year, and country, 2) to describe any dispensed etoricoxib prescribed by dentists that was not associated with dental procedures, 3) to describe off-label use of etoricoxib among patients aged less than 16 years and with doses >90 mg/day including the associated dental procedures, patient demographics, dosing, year, and country, 4) and to describe the duration of use of etoricoxib and the number of tablets dispensed.

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## Study status

Finalised

# Research institutions and networks

## Institutions

Department of Epidemiology, Institute of Applied Economics and Health Research (ApHER)

 Denmark

**First published:** 22/02/2013

**Last updated:** 01/07/2019

Institution

Outdated

EU Institution/Body/Agency

ENCePP partner

Institute of Applied Economics and Health  
Research Copenhagen, Denmark, National  
Institute of Public Health, University of Southern  
Denmark Copenhagen, Denmark, School of Public  
Health, University of Tampere Tampere, Finland,  
Department of Health Management and Health  
Economics, University of Oslo Oslo, Norway,  
University of Gothenburg, Centre for Health  
Economics Gothenburg, Sweden

## Contact details

### **Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.  
ClinicalTrialsDisclosure@merck.com

**Study contact**

[ClinicalTrialsDisclosure@merck.com](mailto:ClinicalTrialsDisclosure@merck.com)

### **Primary lead investigator**

Anders Green

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 25/04/2013

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## **Study start date**

Actual: 24/07/2014

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## **Data analysis start date**

Planned: 12/06/2017

Actual: 30/05/2017

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## **Date of final study report**

Planned: 27/11/2017

Actual: 27/11/2017

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Merck Sharp & Dohme Corp.

# Study protocol

[0663-170-00\\_final-redaction.pdf](#) (702.91 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:**

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:**

The primary study objective is to characterize dispensed etoricoxib prescribed by dentists, including off-label use.

## Study Design

## **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Non-interventional, population-based study of dispensed etoricoxib prescriptions in dental practice in the Nordic countries

## Study drug and medical condition

### **Medicinal product name, other**

Arcoxia

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### **Medical condition to be studied**

Dental care

## Population studied

### **Short description of the study population**

All individuals in the four Nordic countries in the period 2012-2013 with dispensed etoricoxib prescribed by dentists.

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### **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)
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### **Estimated number of subjects**

1000

## Study design details

### **Outcomes**

To describe: 1) dental prescriptions including the associated procedures, patient demographics, dosing, year, and country. 2) Use by dentists not associated with dental procedures. 3) Off-label use in patients <16 years of age and with doses >90 mg/day. 4) Duration of dental prescriptions and number of tablets dispensed. 5) Patients with concurrent prescriptions for anticoagulants.

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### **Data analysis plan**

Descriptive analyses: 1) Distribution of dental procedures in patients with etoricoxib prescribed by a dentist 2) Distribution of the etoricoxib prescriptions overall and stratified by dose, patient demographics, year, and country. 3) Distribution of etoricoxib prescriptions, which are associated / not associated with one or more defined dental procedures 4) Distribution of off-label use (>90 mg, <16 years of age) 5) Description of number of patients with concurrent prescriptions for anti-coagulants

## Documents

### **Study results**

[p170mk0663-final-report\\_final-redaction.pdf](#) (3.15 MB)

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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), other**

National Health Registries Denmark, National Health Registries Finland, National Health Registries Sweden, National Health Registries Norway

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

## 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**

Unknown