Etoricoxib Prescribing Patterns and Adverse Events of Interest during Etoricoxib Treatment in UK Primary Care (MK-0663-162)

First published: 04/05/2017

Last updated: 11/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17526

Study ID

19307

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

This postmarketing study was conducted to describe prescribing patterns for etoricoxib(ARCOXIA)® in General Practice and describe the incidence of selected adverse events recorded in the United Kingdom (UK) Medicines and Health Care Products Regulatory Agency (MHRA) General Practice Research Database (GPRD).

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.
ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Dena Rosen Ramey, BA

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 23/03/2006

Study start date

Actual: 30/06/2006

Data analysis start date

Actual: 01/03/2015

Date of final study report

Actual: 23/11/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

Study protocol

0663-162 Protocol_final-redaction.pdf (1.96 MB)

0663-162 Protocol Amendment_final-redaction.pdf (1.01 MB)

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

Study number: MK-0663-162NCT number: NCT01685424

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Etoricoxib Prescribing Patterns and Adverse Events of Interest

Data collection methods:

Secondary use of data

Main study objective:

To evaluate characteristics of patients prescribed etoricoxib, patterns in the prescribing of etoricoxib by general practitioners, and to estimate the absolute incidence rate of adverse events among new users of etoricoxib.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ETORICOXIB

Medical condition to be studied

Osteoarthritis

Rheumatoid arthritis

Ankylosing spondylitis

Gout

Population studied

Short description of the study population

All patients in the Medicines and Health Care Products Regulatory Agency's (MHRA’s) CPRD GOLD who have at least one electronic outpatient prescription record for etoricoxib issued during the period (1 April 2002 to 31 December 2011) at the date of query execution against the data warehouse.

Age groups

- 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)

Estimated number of subjects

79189

Study design details

Outcomes

1. Dose of Initial Etoricoxib Prescription2. Duration of Initial Etoricoxib Prescription 3. Participants Baseline Characteristics (Demographics and Medical) 4. Incidence of Adverse Events of Special Interest Among Etoricoxib Users, 1. "Off-label" use of Etoricoxib

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Data analysis plan

All data analyses were purely descriptive and no statistical hypothesis testing was conducted in this observational study.

Documents

Study results

0663-162 Final Study Report_final-redaction.pdf (3.3 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 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