Febuxostat-5006: Drug Utilization Study to Describe the Pattern of Febuxostat Use in Relationship to Allopurinol Following Addition of the Boxed Warning and Modification of the Indication Based on the Results of the CARES Trial (Febuxostat Drug Utilization Study)

First published: 20/04/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS40179

Study ID

48592

DARWIN EU® study

No

Study countries

United States

Study description

The prescribing information provides information on medicines. This study will check the number of patients starting febuxostat and the number of febuxostat users with cardiovascular disease after changes to the prescribing information.

Study status

Finalised

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda trialdisclosures@takeda.com

Study contact

trialdisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/01/2021

Study start date

Actual: 15/08/2020

Data analysis start date

Actual: 05/01/2021

Date of final study report

Planned: 30/06/2021

Actual: 30/06/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

Study protocol

Febuxostat-5006_Protocol-V2-Redacted.pdf (642.89 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Primary objective of the study is to describe the number and proportion of patients initiating febuxostat as new users (that is, without previous allopurinol

therapy) versus prevalent new users (ie, with previous allopurinol therapy) of ULT and to describe the number and proportion of febuxostat users with established CVD.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Descriptive study

Study drug and medical condition

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

FEBUXOSTAT

Medical condition to be studied

Gout

Myocardial infarction

Angina unstable

Haemorrhagic stroke

Ischaemic stroke

Transient ischaemic attack

Peripheral vascular disorder

Population studied

Short description of the study population

The study population included gout patients aged 21 years or older initiated febuxostat therapy on or after 01 June 2016 identified from the Optum Clinformatics DataMart (CDM) and the IQVIA PharMetrics Plus claims database.
Inclusion criteria:
• Index fill date on or after 01 June 2016.
• Having at least one diagnosis for gout (identified with diagnosis codes, International Classification of Diseases [ICD]-9-CM: 274.x or ICD-10: M10.x) at any time in the patient's record.
• Age ≥21 years at index fill date.
• Continuously enrolled for at least 12 months prior to index fill date.

Age groups

- 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)

Special population of interest

Other

Special population of interest, other

Patients with gout

Estimated number of subjects

24.046

Study design details

Outcomes

The primary outcomes will assess the number of participants newly initiating febuxostat therapy versus prevalent new users and number of participants with established cardiovascular disease (CVD).

Data analysis plan

Standard descriptive statistics method will be used to report mean, standard deviation, median, range, temporal trends to describe the dispensing pattern of febuxostat.

Documents

Study results

Febuxostat-5006 RDS 2021-06-30.pdf (643.96 KB)

Data management

Data sources

Data source(s), other

IMS LifeLink: PharMetrics Plus - US

Data sources (types)

Administrative healthcare records (e.g., claims)

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

No