

# ARIANE - Arixtra and platelet monitoring (Study of the actual usage of Arixtra® 2, 5 mg in general practice)

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## General

### Identification

Detailed name Arixtra and platelet monitoring (Study of the actual usage of Arixtra® 2, 5 mg in general practice)

Sign or acronym ARIANE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL : 907260

### General Aspects

Medical area General practice

Others (details) Thrombosis

Keywords platelet monitoring, pharmaco-epidemiology, observational, thromboprophylaxis

### Scientific investigator(s) (Contact)

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Unit Laboratoire GSK

### Collaborations

### Funding

Funding status Private

Details GSK laboratory

## Governance of the database

Sponsor(s) or organisation(s) responsible      Laboratoire GSK

Organisation status      Private

## Additional contact

## Main features

### Type of database

Type of database      Study databases

Study databases (details)      Not-repeated cross-sectional studies (except case control studies)

Database recruitment is carried out by an intermediary      A selection of health care professionals

Database recruitment is made on the basis of:      Medication(s) taken

Database recruitment is carried out as part of an interventional study      No

Additional information regarding sample selection.      Investigators will be selected via random drawing using a complete sampling frame of the general practitioners exercising in metropolitan France (source: CEGEDIM file. During the entire period of inclusion, the investigating doctor will keep a registry of the eligible patients receiving ARIXTRA® 2.5 mg or an LMWH in thromboprophylaxis. The registry will make it possible to ensure representativeness of patients for whom the doctor will complete the medical questionnaires

## Database objective

Main objective      Evaluate and compare in general practice the level of prescription for platelet monitoring of patients receiving Arixtra® 2.5 mg (fondaparinux sodium) or an LMWH (low-molecular-weight heparin) in venous thromboprophylaxis.

Inclusion criteria      ? Patient of at least 18 years of age  
? Bedridden patient or with reduced mobility  
Patient for whom a treatment via ARIXTRA® 2.5 mg or an LMWH is initiated within the framework of venous thromboprophylaxis

## Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	France
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## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY)	2008
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Date of last collection (YYYY or MM/YYYY)	2009
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### Size of the database

Size of the database (number of individuals)	[500-1000[ individuals
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Details of the number of individuals	910
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### Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data
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Clinical data (detail)	Medical registration
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Declarative data (detail)	Face to face interview
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Presence of a biobank	No
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Health parameters studied	Health care consumption and services
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Care consumption (detail)	Medicines consumption
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## Procedures

Data collection method	Registry, medical questionnaire
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Participant monitoring	No
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Links to administrative sources	No
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## Promotion and access

### Promotion

### Access

Terms of data access (charter for data provision, format of data, availability delay)	Accepted for publication in "La Presse médicale"
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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