

# 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)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[500-1000[ individuals
Details of the number of individuals	910
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Medical registration
Declarative data (detail)	Face to face interview
Presence of a biobank	No
Health parameters studied	Health care consumption and services
Care consumption (detail)	Medicines consumption

Procedures	
Data collection method	Registry, medical questionnaire
Participant monitoring	No
Links to administrative sources	No
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"
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only