

# Safety Alerts: An Observational Study in Portugal (Safety alerts)

**First published:** 03/02/2016

**Last updated:** 29/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11977

---

### Study ID

17084

---

### DARWIN EU® study

No

---

### Study countries

 Portugal

---

### Study description

An observational study of all alerts published on the INFARMED website from January 2002 through December 2014. From the data included in the alerts, the following information was extracted: active substance name (and trade name),

event that led to the alert, and the resulting safety measures. Active substances were classified according to the Anatomical Therapeutic Chemical (ATC) code.

---


## Study status

Finalised

## Research institutions and networks

### Institutions

Department of Medical Sciences Institute of Biomedicine, University of Aveiro

 Portugal

**First published:** 04/01/2016

**Last updated:** 04/01/2017

Institution

Outdated

Educational Institution

ENCePP partner

## Contact details

### Study institution contact

Maria Teresa Herdeiro [teresaherdeiro@ua.pt](mailto:teresaherdeiro@ua.pt)

Study contact

[teresaherdeiro@ua.pt](mailto:teresaherdeiro@ua.pt)

### Primary lead investigator

Maria Teresa Herdeiro

Primary lead investigator

## Study timelines

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

Planned: 17/09/2012

Actual: 17/09/2013

---

### **Study start date**

Planned: 07/01/2013

Actual: 04/02/2013

---

### **Date of final study report**

Planned: 01/07/2015

Actual: 15/07/2015

## Sources of funding

- Other

## More details on funding

Internal funding

## Regulatory

**Was the study required by a regulatory body?**

No

---

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

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Analysis and description of safety alerts

**Data collection methods:**

Secondary use of data

---

**Main study objective:**

This study sought to analyze all safety alerts published by the Portuguese National Authority of Medicines and Health Products I.P. (INFARMED).

## Study Design

## **Non-interventional study design**

Other

---

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

Sentinel sites

# Population studied

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

Portuguese population

---

### **Age groups**

- Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - 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)
- 

## **Estimated number of subjects**

0

# Study design details

## **Data analysis plan**

We conducted an observational study of all alerts published on the INFARMED website from January 2002 through December 2014. From the data included in the alerts, the following information was abstracted: active substance name (and trade name), event that led to the alert, and the resulting safety measures. Active substances were classified according to the Anatomical Therapeutic Chemical (ATC) code.

## Documents

### Study publications

[Soares S, Roque F, Teixeira Rodrigues A, Figueiras A, Herdeiro MT. Safety Alerts...](#)

---

## 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)

[Other](#)

---

### Data sources (types), other

Safety alerts, Infarmed website

## 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