

# THE ASSESSMENT OF SAFETY PROFILE AND TOLERANCE OF ZOLEDRONIC ACID ACTAVIS® FORMULATION IN POLISH PATIENTS POPULATION

**First published:** 12/05/2015

**Last updated:** 08/05/2017

Study

Planned

## Administrative details

### EU PAS number

EUPAS9727

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### Study ID

18996

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### DARWIN EU® study

No

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### Study countries

Poland

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### Study description

Post Authorization Safety Study has been initiated on the company's own initiative with no obligation requested by any Health Authorities. Nor there are any additional activities requested beyond routine PhV activities in RMP. Product is registered since April 20th, 2012, there are 13 brands on the Polish market containing the same active substance and what should be emphasized, product safety was and will continue to be evaluated through routine PhV activity. Recommendations being the outcome of list of signals discussed at PRAC since September 2012 i.e. Osteonecrosis of the external auditory canal, have been implemented in product information. Therefore believing that product safety is adequately monitored with routine activities and appropriate actions are taken when necessary, voluntary PASS project will not be further pursued.

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### **Study status**

Planned

## Research institutions and networks

### Institutions

**Euopharma**

**First published:** 01/02/2024

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**Institution**

## Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

JERZY CHUDEK

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 12/05/2015

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**Study start date**

Planned: 15/05/2015

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**Date of final study report**

Planned: 31/12/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ACTAVIS

# Study protocol

[Zolderonic protocol 2015 04 27 eng final form.pdf](#) (1.06 MB)

## Regulatory

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

Yes

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

Not applicable

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

**Main study objective:**

Assessment of safety profile of ZOLEDRONIC ACID ACTAVIS in patients with advanced malignancy involving bone.

## Study Design

## **Non-interventional study design**

Other

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

PASS study, non-interventional post-marketing study

## Population studied

### **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)
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### **Estimated number of subjects**

3500

## Study design details

### **Outcomes**

Assessment of the tolerance of the treatment.

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### **Data analysis plan**

This is a descriptive study, evaluating safety and tolerance of treatment with study drug, thus in this study basic statistical analysis will be performed by statistical and epidemiological methods, analyse by Statistica version 10. On the basis of reported adverse events, the frequency of their occurrence in study population will be assessed. For the most common adverse events the

characteristics of subpopulation in which it was reported will be analyzed.

## 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](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No