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

Study ID

18996

DARWIN EU® study

No

Study countries

Poland

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.

Study status

Planned

Research institutions and networks

Institutions

Europharma

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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

Study start date

Planned: 15/05/2015

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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)

Estimated number of subjects

3.500

Study design details

Outcomes

Assessment of the tolerance of the treatment.

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, analise by Statistica version 10.On the basis of reported adverse events, the frequency of their occurrence in study population will be assessed. For the mostcommon 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

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No