Non-interventional study with Binosto 70 mg effervescent tablets once weekly investigating gastro-intestinal events and medication errors (Gastro-PASS)

First published: 04/09/2015

Last updated: 02/07/2024

Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/33495

EU PAS number

EUPAS10888

Study ID

33495

DARWIN EU® study

No

Study countries

☐ Italy

☐ Spain

Study description

Binosto (effervescent alendronate) has been developed with the aim of further reducing the risk of esophageal irritation, incl. the risk of tablet adhesion to the esophagus wall. In addition it is the aim to provide a convenient dosage form that would ensure better compliance across the patient population. The safety profile of Binosto will be evaluated in a real-life setting. The present study will investigate the upper gastrointestinal adverse events and medication errors associated with once weekly administration of Binosto.

Study status

Planned

Research institutions and networks

Institutions

OXON Epidemiology

☐ Spain

☐ United Kingdom

First published: 06/12/2010

Last updated: 15/03/2024

Institution **Laboratory/Research/Testing facility** **Non-Pharmaceutical company**

ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 03/07/2014

Study start date

Planned: 30/06/2017

Date of final study report

Planned: 31/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

EffRx Pharmaceuticals SA

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The main objective of the study is to investigate known safety concerns (oesophageal toxicity, gastritis, gastric ulcers, duodenitis) and medication errors of the class of oral bisphosphonates, which may be relevant for the new product, alendronic acid 70 mg effervescent tablets (Binosto), which represents a new pharmaceutical formulation of alendronate.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Binosto

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

1200

Study design details

Outcomes

To calculate the cumulative incidence of GI ADRs (individual reactions and composite events*) of Binosto. Co-primary objective: To calculate the percentage of patients with medication errors of Binosto. - To evaluate persistence, discontinuation and reason, and compliance with SmPC.- To compare the frequency of upper GI AEs collected in the prospective cohort with

historical upper GI AEs in a cohort of patients on Alendronate 70mg.- To calculate the incidence rate of Binosto individual gastric AEs.

Data analysis plan

Analyses will be mainly descriptive for the overall study population and subgroups. Comparisons will be made at baseline between with Binosto and the non-concurrent cohort. For the longitudinal phase, the cumulative incidence (proportion) of the primary and secondary endpoints will be calculated with 95% confidence intervals. Univariate study of differences between with Binosto and the non-concurrent cohort will be made in the frequency and incidence of upper gastrointestinal adverse events, using chi-square tests and relative incidence rates with 95% confidence intervals. The proportion (and 95% confidence intervals) of subjects with medication errors will be calculated. Persistence and discontinuation will be analysed using Kaplan-Meier curves. The incidence rates and their 95% confidence interval for solicited individual gastric AEs, at each of the three follow up visits and, globally, at the end of the prospective study, will be calculated.

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

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