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: 03/06/2026

Study Finalised

Administrative details

EU PAS number

EUPAS10888

Study ID

33495

DARWIN EU® study

No

Study countries

Italy

Spain

Study description

Binosto® (effervescent alendronate) was developed with the aim of reducing the risk of oesophageal irritation, including the risk of tablet adhesion to the oesophageal wall. In addition, it was designed to provide a convenient dosage form that may improve treatment compliance among patients.

The safety profile of Binosto will be evaluated in a real-world clinical setting. This study will investigate upper gastrointestinal adverse events and medication errors associated with once-weekly administration of Binosto.

Study status

Finalised

Research institutions and networks

Institutions

OXON Epidemiology

Spain

United Kingdom

First published: 06/12/2010

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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

Actual: 24/05/2017

Date of final study report

Planned: 31/07/2020

Actual: 05/03/2021

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Prospective, observational, multicenter, multinational, single arm, postauthorization safety study (PASS)

Main study objective:

The primary objective of the study is to investigate known safety concerns associated with oral bisphosphonates, namely oesophageal toxicity, gastritis, gastric ulcers and duodenitis, as well as medication errors that may be relevant to alendronic acid 70 mg effervescent tablets (Binosto), a novel pharmaceutical formulation of alendronate.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BINOSTO ONCE WEEKLY

Medicinal product name, other

Binosto

Study drug International non-proprietary name (INN) or common name

ALENDRONATE SODIUM TRIHYDRATE

Anatomical Therapeutic Chemical (ATC) code

(M05BA04) alendronic acid

alendronic acid

Population studied

Short description of the study population

Inclusion criteria were patients newly prescribed ALN EFF and naïve to bisphosphonate therapy; women with osteoporosis; written informed consent; and the ability to comply with the requirements of the study. Patients with a history of upper GI symptoms were also included. Exclusion criteria were the presence of any contraindications to ALN EFF according to Summary of Product Characteristics (SmPC).

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

Data analysis plan

Analyses will be mainly descriptive for the overall study population and subgroups. Comparisons will be made at baseline between the Binosto cohort 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. A univariate analysis of differences between the Binosto cohort and the non-concurrent cohort will be conducted for 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 intervals for solicited individual gastric AEs, at each of the three follow-up visits and overall at the end of the prospective study, will be calculated.

Summary results

Patients (N = 1028) aged 67 ± 9 years (mean ± SD) received ALN EFF weekly. The cumulative incidence of upper GI AEs (oesophageal toxicity, gastritis, gastric ulcers, and duodenitis) related to ALN EFF (primary endpoint) was 9.6% (95% confidence interval [CI] 7.9–11.6%), the vast majority being of mild intensity. The most frequently occurring upper GI AEs related to ALN EFF were dyspepsia (2.7%), gastroesophageal reflux disease (2.4%), and nausea (2.2%). None of the relevant upper GI AEs listed in the primary endpoint and no serious AEs were reported. At least one medication error occurred in 29.9% (95% CI 27.1–32.8%) of patients. However, the majority of medication errors were associated with administration instructions applicable to any oral bisphosphonate and only seven medication errors were associated with the ALN EFF formulation. ALN EFF was discontinued in 209 of 1028 (20.3%) patients. The most frequent reasons for discontinuation were AEs related to ALN EFF (46.9%) and patients' decision (42.6%). Compliance with ALN EFF was high, reflected by

a mean Morisky Green score of 92.8 ± 18.6. PMW with osteoporosis treated with ALN EFF in a real world setting experienced few upper GI AEs. In addition, they had a low discontinuation and high compliance compared with other formulations, suggesting that ALN EFF may increase patient satisfaction and therefore long term adherence and efficacy.

Documents

Study publications

Salvatore Minisola, Antonio P Vargas, Giulia Letizia Mauro, Fernando Bonet Madu…

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 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