# Observational prospective cohort study to evaluate the incidence of adverse events (AE), risk factors, and drug utilization patterns related to treatment with BUSCAPINA COMPOSITUM N from March to December 2016 in patients from Metropolitan Lima (PASS PERU)

**First published:** 31/08/2016

**Last updated:** 19/10/2026

Study Finalised

## Administrative details

**EU PAS number**

EUPAS15008

**Study ID**

15009

**DARWIN EU® study**

No

**Study countries**

Peru

**Study description**

What AE occur in routine clinical practice, what is the incidence of AE and ADR, how many patients present with AE symptoms related to a potential liver injury. What are the drug utilization patterns in patients, what are the predisposing factors for the occurrence of adverse events and adverse drug reactions.

**Study status**

Finalised

# Research institutions and networks

## Institutions

Magaly Blas

Boticas InkaFarma Lima, Mifarma Lima, Arcángel Lima, Boticas y Salud Lima, Nortfarma Lima, Seguro Social de Salud Lima, Clínica Internacional Lima, Clínica Médica Cayetano Heredia Lima, América Salud Lima, Corporación Boticas Perú Lima

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Magaly Blas

Primary lead investigator

# Study timelines

**Date when funding contract was signed**

Planned: 21/12/2015

**Study start date**

Planned: 05/09/2016

**Data analysis start date**

Planned: 12/09/2016

**Date of final study report**

Planned: 05/07/2017

Actual: 31/03/2017

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Boehringer Ingelheim

## Study protocol

Pharmacovigilance Plan Buscapina Compositum N - Submitted document 2015DEC28.pdf (224.79 KB)

## Regulatory

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

Yes

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

Not applicable

## Other study registration identification numbers and links

218.705, NCT02910167

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Study design:**

This is a 12-month active pharmacovigilance, prospective, cohort multicenter study

**Main study objective:**

1.) Identify and describe the AE and adverse drug reactions (ADR) presented in patients that are undergoing treatment with BUSCAPINA COMPOSITUM N in Metropolitan Lima.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Buscapina Compositum N

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

HYOSCINE BUTYLBROMIDE

PARACETAMOL

**Medical condition to be studied**

Pain

# Population studied

**Short description of the study population**

Patients 18 years of age and older who have received at least one dose of BUSCAPINA COMPOSITUM N according to label indications

**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**

360

# Study design details

**Setting**

15 patient recruitment centers (Clinics, private doctor´s office and pharmacies). We will prioritize the clinics, pharmacies and private doctor’s office with the highest volume of BUSCAPINA COMPOSITUM N sales.

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**Outcomes**

Occurence of AEs in routine clinical practice in patients that are in treatment with BUSCAPINA COMPOSITUM N (when it is used according to the label indications), Incidence of AE and ADR in patients that are in treatment with BUSCAPINA COMPOSITUM N when it is used in routine clinical practice according to label indicationsFrequency of patients present with AE symptoms related to a potential liver injuryDrug utilization patterns in patients who receive BUSCAPINA COMPOSITUM N in pharmacies, clinics and private doctor¿s office in Metropolitan Lima Peru

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**Data analysis plan**

1. For the first objective of the study a descriptive statistical analysis of frequencies will be conducted for the adverse events that are discovered. 2. For the second objective of the study, If data is available the incidence rate will be calculated including in the numerator the number of cases of people who develop an adverse event, and in the denominator the sum of the different amounts of person time that each participant in the study contributes. 3. For the third objective, we will complete a descriptive statistical analysis related to the drug utilization patterns in all patients. and compare patterns between those with and without AE.4. For the fourth objective, we will conduct a logistic regression analysis to identify risk factors (such as past medical history, concomitant illnesses, drug utilization factors of the medication, and concomitant treatments) in patients that present with AE and adverse drug reactions related to treatment with BUSCAPINA COMPOSITUM N.

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**Summary results**

The mean number of treatment days of Buscapina Compositum N was 3.0 (SD:0.9) and the average daily dose was 2.1 (SD: 0.7). Overall, 4.7% patients who participated in the Buscapina Compositum N cohort study had an adverse event, none was related to potential liver damage. Twelve of these patients had one adverse event and 4 had two adverse events, making a total of 20 events. The majority of adverse events were from the gastrointestinal tract (55%, 11/20), followed by nervous system disorders (35%; 7/20) and respiratory (5%; 1/20) and urinary tract disorders (5%; 1/20). None of the adverse events were serious, 16 out of 20 adverse events (80%) were classified as related and the remaining 4 (20%) as not related to Buscapina Compositum N.

## Documents

**Study results**

0218-0705_Synopsis.pdf (134.32 KB)

# 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