# Evaluation of the Safety and Effectiveness of Lastacaft® Ophthalmic Solution 0.25%(Alcaftadine) for the Prevention of Itching Associated with Allergic Conjunctivitis: A Postmarketing Surveillance Study in Korea

**First published:** 14/12/2016

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS16675

**Study ID**

27008

**DARWIN EU® study**

No

**Study countries**

☐ Korea, Democratic People's Republic of

**Study description**

Objective: To evaluate the safety and effectiveness of Lastacaft® for the prevention of itching associated with allergic conjunctivitis through active surveillance under routine clinical practice. The specific aims are to report on the: 1. Serious adverse events or adverse drug reactions 2. Unexpected adverse drug reactions that are not listed in the precautions for use in the product label (hereafter referred to as unexpected adverse drug reactions) 3. Known adverse drug reactions 4. Non-serious adverse events 5. Effectiveness of Lastacaft as measured by a change from baseline in the patient’s assessment of itching associated with allergic conjunctivitis The study will sequentially enroll at least 3,000 Korean patients at participating sites who are treated with Lastacaft Ophthalmic Solution 0.25% (hereafter referred to as Lastacaft) at the labeled dose, as per clinical practice. Only those patients who have consented to the study and who have signed the private information protection act form or ICF will be included in the study. Safety information and effectiveness, as assessed by the patient, will be collected during any in-office visit within approximately 2 weeks of starting treatment with Lastacaft. Safety information and the patient’s assessment of effectiveness may also be collected via telephone contact if patients do not have an in-office visit during this period. Study will be completed within after product approval or when at least 3,000 patients have completed the study. Periodic and final reports will be sent to MFDS according to the schedule per regulation

**Study status**

Finalised

## Research institutions and networks

## Institutions

### DreamCIS

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

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

Anita Verga CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

**Primary lead investigator**

Anita Verga

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 30/07/2012

Actual: 01/11/2016

---

**Study start date**

Planned: 24/09/2012

Actual: 19/10/2015

**Date of final study report**
Planned: 28/09/2018

Actual: 20/09/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Allergan

## Study protocol

Protocol 229666-007 PMS Korea Amd 2 FINAL 28Aug2015 D1.pdf(399.6 KB)

## Regulatory

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

Yes

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

Non-EU RMP only

## Other study registration identification numbers and links

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

---

**Main study objective:**

The specific aims are to report on the: 1. Serious adverse events or adverse drug reactions 2. Unexpected adverse drug reactions that are not listed in the precautions for use in the product label 3. Known adverse drug reactions 4. Non-serious adverse events 5. Effectiveness as measured by a change from baseline in the patient's assessment of itching associated with allergic conjunctivitis

## Study Design

**Non-interventional study design**

Cohort

Other

---

**Non-interventional study design, other**

Intensive monitoring schemes, Active surveillance

## Study drug and medical condition

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

ALCAFTADINE

## Population studied

**Short description of the study population**

Korean patients treated with Lastacaft for the prevention of itching associated with allergic conjunctivitis according to the approved label. This includes treatment of patients who were experiencing or anticipating symptoms of itching associated with allergic conjunctivitis, and for whom administration of Lastacaft has been decided.

---

**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**

3000

## Study design details

**Data analysis plan**

Statistical analyses will be performed to gain an understanding of the qualitative and quantitative nature of the data collected and the characteristics of the samples studied. Continuous variables (eg, age) will be summarized using the descriptive statistics including the number of non-missing observations, mean, standard deviation, median, minimum, and maximum values by visit. Categorical variables (eg, gender) will be summarized by the frequency counts and percentages in each category. Patients that use study treatment off-label will be analyzed separately. Patients that use Lastacaft for more than 3 months will be classified as “long-term users”. Long-term users will be analyzed separately.

## Documents

**Study results**

Korean Lastacaft Abstract.pdf(38.61 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**

Unknown