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

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Institution

Contact details

Study institution contact

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Study contact

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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

3.000

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