Abstract

Title

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

Keywords

Lastacaft, allergic conjunctivitis, non-interventional

Rationale and background

The rationale of this prospective, observational postmarketing surveillance (PMS) study is to evaluate the safety and effectiveness of Lastacaft® for the prevention of itching associated with allergic conjunctivitis as required by the Korea Ministry of Food and Drug Safety (MFDS).

Research question and objectives

The objectives of the study include summarizing the frequency of:

- Serious adverse events or adverse drug reactions
- 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)
- Known adverse drug reactions
- Non-serious adverse events
- Effectiveness of Lastacaft as measured by a change from baseline in the patient's assessment of itching associated with allergic conjunctivitis

Study design

This study was a non-interventional study, which sequentially enrolled eligible Korean patients treated with Lastacaft, with a signed private information protection act form or informed consent form (ICF), at each of the selected sites until a minimum of 3,000 patients completed one follow-up contact during the study period. The decision to treat a patient with Lastacaft is determined by the physician and patient prior to the decision to include the patient in the study.

Safety and effectiveness data was collected at all follow-up in-office visits within approximately 2 weeks of starting treatment with Lastacaft. Data was collected by assessing and interviewing patients, and/or reviewing medical charts. If a patient did not schedule a follow-up in-office visit within 2 weeks (+/- 1 week) of starting treatment with Lastacaft, the investigator or his/her designee contacted the patient by telephone to collect follow-up safety information as well as the patient's assessment of effectiveness.

Setting

Lastacaft is expected to be mainly used in university hospitals, general hospitals, and clinics that have an ophthalmology department; therefore, surveillance was mainly conducted by collecting relevant information on treated patients from contracted specialists at these locations.

Patients and study size, including dropouts
During the study, case report forms (CRFs) of a total of 3,363 subjects were retrieved. Among the subjects whose CRFs were retrieved, a total of 3,157 subjects were included in the safety assessment, excluding 9 subjects in 'Subjects who have consented prior to the contract date', 20 subjects in 'Subjects administered the Lastacaft prior to the contract date: Includes subjects whose Lastacaft administration was confirmed in concomitant medications',

95 subjects in 'Subjects administered the Lastacaft prior to the consent date', 8 subjects in 'Subjects who didn't receive Lastacaft for this study', 48 subjects in 'Follow-up failure: Subjects for whom adverse event status (Adverse Events status is unknown or missing in CRF) could not be established', 18 subjects in 'Subjects who violate the dosage', 2 subjects in 'Subjects who are less than or equal to 2 years old', and 6 subjects in 'Subjects who are foreigners'. Of these, 3,123 subjects were included in the effectiveness assessment excluding 34 subjects in 'Subjects who are assessed as "Unassessible" on the Final Efficacy Assessment'.

Variables and data sources
All adverse events that occur during treatment and for 30 days after the last dose of Lastacaft, regardless of causality, were captured. The safety assessment included all undesirable changes of medical findings (including laboratory test findings) and all adverse events associated with Lastacaft administration.
The following information was collected for the surveillance of adverse events:

- presence or absence of an adverse event
- adverse event term
- start/end date of adverse event
- severity of adverse event
- whether the adverse event met the criteria for a serious adverse event
- outcome of adverse event
- causality with this drug
- actions taken

The effectiveness of Lastacaft treatment for the prevention of itching associated with allergic conjunctivitis was assessed based on ocular itching. Ocular itching was evaluated by asking the patient to provide a numerical rating for ocular itching at baseline and once within approximately 2 weeks of starting treatment with Lastacaft.

Results

During the study period, 224 AEs occurred in 194/3,157 subjects in the safety analysis set (6.15%). In detailed analysis of AEs, 'DRUG INEFFECTIVE' occurred in 2.95% (93/3,157 subjects), 'EYE PAIN' in 1.30% (41/3,157 subjects), 'OCULAR HYPERAEMIA' in 0.67% (21/3,157 subjects), etc. in that order were the most commonly reported AEs. A total of 101 (3.20%) patients discontinued alcaftadine treatment as a result of AEs. The severity of the AEs was mostly mild (93.30%, 209/224 AEs). There were no Serious Adverse Events related to Lastacaft reported during the surveillance period. Lastacaft is also considered effective in

96.70% (3,020/3,123) of subjects in the prevention of itching associated with allergic conjunctivitis.

Conclusion

In conclusion, the PMS study of Lastacaft showed no new significant information affecting safety and effectiveness of the study drug. Therefore, the use of Lastacaft for the prevention of itching caused by allergic conjunctivitis is considered safe and effective. Although the overall AE incidence is low reflecting the real-world treatment and reporting experience, the safety profile of Lastacaft derived from this study is consistent with the current Prescribing Information of Lastacaft 0.25% Opthalmic Solution. Information from this study would supplement the safety and effectiveness data already available as part of the regulatory commitment. Lastacaft will continue to be monitored through future voluntary reports and studies.