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Committee for Medicinal Products for Human Use (CHMP)

Assessment report

Aerius
Azomyr
Neoclarityn

desloratadine

Procedure No.: EMEA/H/C/000313/A45/0057
EMEA/H/C/000310/A45/0057
EMEA/H/C/000314/A45/0057

CHMP assessment report for paediatric use studies submitted according to Article 45 of the Regulation (EC) No 1901/2006

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

Disclaimer: The assessment report was drafted before the launch of the European Medicines Agency's new corporate identity in December 2009. This report therefore has a different appearance to documents currently produced by the Agency

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I. INTRODUCTION

As requested by the *Guidance To Marketing Authorisation Holders For the Provision Of Additional Paediatric Data Not Yet Submitted To the EMEA (Doc. Ref. EMEA/157537/2005 Rev; dated 10 May 2005)*, the MAH submitted, on 15 July 2005, to EMEA, the Rapporteur and the Co-Rapporteur data concerning the use of desloratadine products in children up to the age of 18 years. Later, on 6 February 2008, the MAH submitted the Clinical Study Report for the clinical study P04141, which was not yet finalised in July 2005.

Now the MAH is submitting the only recently finalised Clinical Study Report for the last remaining study P04299:
Observational Study Evaluating the Safety and Efficacy of Desloratadine for Perennial Allergic Rhinitis in Indonesian Paediatric Patients. This submission, same as the previous two, is not done on the grounds of pedriatric requirements (i.e. art 45 or 46) but in accordance with the above quoted EMEA Guidance.

II. SUBMITTED DATA

Clinical Study Report Study P04299: Observational Study Evaluating the Safety and Efficacy of Desloratadine for Perennial Allergic Rhinitis in Indonesian Paediatric Patients.

Synopsis
Studied Period: 20 May 2005 – 31 March 2008

Objective:
The aims of this observational study are to evaluate the safety and general clinical response of desloratadine syrup in the relief of symptoms associated with perennial allergic rhinitis in Indonesian pediatric patients.

Methodology:
Open-label, observational study.
The patient's diagnosis, initiation of treatment and the necessary monitoring and follow-up visits will depend on the underlying medical condition and the treatment prescribed, according to the doctor's daily practice.
Demographic data will be collected; each of symptoms as parameters will be graded and scored, concomitant therapy (desloratadine syrup) will be noted at first visit by the doctor.
The patient will return for a second study related visit in minimum of 7 days after initiation of therapy. Therapy response will be evaluated and the occurrence of any adverse event will be monitored. All drugs will be used according to the corresponding prescribing information from physician.

Number of subjects:
Approximately 880 patients will be enrolled. This study will be conducted at approximately 8 sites. Each site will enrol approximately 110 patients in order to provide 800 patients that complete this study.

Diagnosis and Criteria for Inclusion

A. inclusion criteria:
- Children patients of both sexes aged between 1-11 years of any race.
- Patients must have unequivocal history of perennial allergic rhinitis. With clinical evidence of allergic rhinitis, including nasal congestion, sneezing, rhinorrhea, pruritus and lacrimation. Minimum score for inclusion: 10.
- Patients must be capable of complying with the dosing regimen.
- Patients must be in general good health; i.e. they must be free of any clinically significant disease (other than allergic rhinitis) that would interfere with study evaluations.
- Patients for whom the use of antihistamine is justified by the investigating doctor.

B. Exclusion criteria
- Patients with asthma who require chronic use of inhaled or systemic corticosteroids.
- Patients with current or history of frequent, clinically significant sinusitis or chronic purulent postnasal drip.
- Patients with rhinitis medicamentosa.
- Patients with a history of hypersensitivity to desloratadine or any of its excipients.
- Patients who according to the doctor's opinion are not suitable for answering in a convenient way to the questions established for this study.

Test Product, Dose, Mode of Administration:
Study drug: Desloratadine syrup
Dosage: 2.5 ml (1.25 mg) once daily for 2-5 years old.
5 ml (2.5 mg) once daily for 6-11 years old.

Description Age of Patients:

Table 1.Description Age of Patients

age of responden

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	1th - 3th	183	31,0	31,0	31,0
	4th - 7th	292	49,4	49,4	80,4
	8th - 11 th	116	19,6	19,6	100,0
	Total	591	100,0	100,0	

Duration of Treatment:
- The duration of the study for each subject will be approximately 7 days.
- Number of visit: minimum two visits

Criteria for Evaluation:
Study variables
Each of symptoms as parameters will be graded and scored, concomitant therapy will be noted at first by the doctor.
The patient will return for a second visit in minimum of 7 days after initiation of therapy.
Therapy response will be evaluated and the occurrence of any adverse event will be monitored.

All drugs will be used according to the corresponding prescribing information from physician.

Statistical Methods:
Descriptive data will be recorded. Descriptive analysis will be performed.

Power and Sample size determination
Using a 95% confidence interval methodology and a sample size of approximately 800 subjects will permit the proportion of subject having a Fair, Good, or Excellent response in global response to be estimated within +/-5%.

Results:
- Efficacy:

Nasal discharge, nasal congestion, nasal itching, sneezing, itching/burning eyes, tearing/watering eyes, redness of eyes, itching of ears or palate revealed significant difference between and after the treatment (p=0.0001).
Based on physician's judgment: 85.4% of subjects were evaluated to have good to excellent condition after treatment with desloratadine. Most of the physicians rated the result of treatment as good: 58.7% (350 subjects), excellent: 26.7% (159 subjects), fair: 8.4% (50 subjects) and poor 1.8% (11 subjects).

- Safety:

Incidence of adverse event was found in 4 subjects. 3 of the subjects experienced nausea and 1 subject experienced dizziness. All of the adverse events were considered mild.

III. CONCLUSION AND RECOMMENDATION

This clinical study does not add very much to the existing knowledge on desloratadine. It is an observational study. There is no control group and it is not blinded. The study duration is very short (7 days). Many biases can occur in a study like this. For example, the patients might have gotten better regardless of treatment and observer bias.
The results are very positive. Nasal discharge, nasal congestion, nasal itching, sneezing, itching/burning eyes, tearing/watering eyes, redness of eyes, itching of ears or palate revealed significant difference between and after the treatment (p=0.0001). In only 4 subjects out of 591 an adverse event was identified. The reported adverse events (nausea and dizziness) are already listed in section 4.8 of the SPC. This clinical study does not change the existing prescribing information of desloratadine.