Clinical Study Synopsis for Public Disclosure

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# Synopsis

**Name of company:** Boehringer Ingelheim  
**Name of finished product:** Alesion®  
**Name of active ingredient:** Epinastine hydrochloride  
**Module:**  
**Volume:**  
**Report date:** 27 October 2009  
**Trial No. / U No.:** 262.293 / U09-2225-01  
**Date of trial:** 01 May 2005 – 23 April 2008  
**Date of revision (if applicable):**  

**Synopsis No.:**

## Title of trial:
Post Marketing Surveillance of Alesion® (epinastine hydrochloride) Dry Syrup -Drug Use-Results Survey of Alesion® Dry Syrup-

## Clinical phase:
IV

## Objectives:
To investigate the safety and efficacy of Alesion® Dry Syrup under the proper use in daily clinical practice in Japanese paediatric patients with allergic rhinitis, eczema/dermatitis, urticaria and pruritus.

## Methodology:
Prospective survey of Aelsion® Dry Syrup under the proper use in daily clinical practice from 12 to 52 weeks

## No. of subjects:
- **planned:** More than 3000  
- **actual:** 3793  
  Treatment: Alesion® Dry Syrup  
  Enrolled:3840  
  Entered:3793  
  Analysed (for safety set):3227

## Diagnosis and main criteria for inclusion:
- Allergic rhinitis, eczema, dermatitis, urticaria, pruritus / Patients with no experience of treatment with epinastine

## Test product:
- **Alesion® Dry Syrup 1%**  
- **dose:** 0.025 - 0.05 g/kg (0.25 - 0.5 mg/kg of epinastine hydrochloride)  
- **mode of admin.:** Oral administration  
- **batch no.:** Not specified (due to marketing product)

## Reference therapy:
- **No reference therapy**  
- **dose:** No reference therapy  
- **mode of admin.:** No reference therapy  
- **batch no.:** No reference therapy
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**Proprietary confidential information**

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### Duration of treatment:
From 12 to 52 weeks

### Criteria for evaluation:

**Efficacy / clinical pharmacology:** Physician’s judgement at week 12 (or at discontinuation or completion of the treatment) after treatment of this product based on disease symptoms.  
**Safety:** Adverse drug reaction

### Statistical methods:
All analyses were performed descriptively.  
For safety analyses, incidence of adverse drug reaction was summarised with respect to patient demographics, baseline conditions and exposure to treatment. Incidence of serious adverse event was summarised separately.  
For efficacy analyses, the percentage of patients assessed as showing “no response” relative to the total number of patients included in the analysis was examined in each of the primary target diseases with respect to patient characteristics.

### SUMMARY – CONCLUSIONS:

**Efficacy / clinical pharmacology results:** A total of 3840 patients from 782 sites were enrolled and case report forms were collected from 3793 patients. Excluded from the analysis set were 537 patients having no subsequent visit after the initial visit, 28 patients having no actual registration and one patient never treated were excluded from analysis set. The safety was assessed based on 3227 patients.  
For the efficacy, 81 patients were excluded from the safety analysis set due to no plausible observation. 3146 patients treated with Alesion® Dry Syrup were included in the efficacy analysis. The vast majority of patients treated with Alesion® Dry Syrup were assessed as showing either “effective” or “minor” response. The percentages of “no response” were varied but ranged as low as 2.47% to 5.56% across the indications for use. The physician’s efficacy assessments are consistent across concerned subgroups in each of the indications.
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**Safety results:**
Out of 3227 patients, 27 patients were reported to have 40 events with adverse drug reaction where the incidence rate of adverse drug reaction was 0.84% (27/3227 patients). The most frequent adverse drug reactions were “nausea” (0.09 %), “dysgeusia” (0.09 %) and “asthma” (0.09 %). “Asthma” was an unlisted adverse drug reaction in the company core data sheet. “Somnolence” is a well-known adverse drug reaction in antihistamines, which was reported in 2 patients (0.06%) in this surveillance.

**Conclusions:**
The safety and efficacy of Alesion® Dry Syrup were assessed in a total of 3227 patients in the surveillance. There were no issues to call new attention to the safety and efficacy. Alesion® Dry Syrup was a highly safe and efficacious drug for daily use in Japanese paediatric patients.

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