

# Post-authorisation safety study of the incidence rate of medication errors before and after the discontinuation of the lower strength vials for Pharmalgen (NI-PH-X-01)

**First published:** 21/09/2018

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS25639

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### Study ID

30408


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### DARWIN EU® study

No

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### Study countries

 Denmark

 United Kingdom

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## Study description

ALK has discontinued production of the lower strengths of Pharmalgen (0.12 µg, 1.2 µg and 12 µg, lower strength vials). Removal of the lower strength vials from the market necessitates a change in the preparation of the up-dosing strengths. The purpose of this study is to characterize safety of Pharmalgen products after removal of the lower strength vials to evaluate if an increase occurs in medication errors or systemic allergic reactions related to medication errors during the up-dosing phase. The data collected for this study will be spontaneously reported individual case safety reports (ICSRs) of medication errors and serious systemic allergic reactions concerning patients in the up-dosing phase of treatment with Pharmalgen (801) *Apis mellifera* or Pharmalgen (802) *Vespula* spp. from the UK.

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## Study status

Finalised

## Research institutions and networks

### Institutions

[ALK-Abelló](#)

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Institution

### Contact details

### **Study institution contact**

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Study contact

[DKHOQPPV@alk.net](mailto:DKHOQPPV@alk.net)

### **Primary lead investigator**

Holst Andreas

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 02/05/2017

Actual: 02/05/2017

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### **Study start date**

Planned: 01/01/2017

Actual: 01/01/2017

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### **Data analysis start date**

Planned: 01/01/2019

Actual: 01/01/2019

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### **Date of final study report**

Planned: 30/06/2019

Actual: 13/05/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

ALK-Abelló A/S

## Study protocol

[PASS protocol Pharmedgen\\_final.pdf](#) (710.18 KB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

### **Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**Main study objective:**

The purpose of this study is to characterize safety of Pharmalgenproducts after removal of the lower strength vials previously used to prepared doses for up-dosing to evaluate if an increase occurs in medication errors or systemic allergic reactions related to medication errors during the up-dosing phase.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective descriptive case study

## Study drug and medical condition

**Medicinal product name, other**

Pharmalgen

## Population studied

## Short description of the study population

Patient who initiates immunotherapy treatment with either Pharmedgen (801) Apis mellifera or Pharmedgen (802) Vespula spp.

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### Age groups

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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)
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### Estimated number of subjects

231

## Study design details

### Data analysis plan

The number of medication errors and serious systemic allergic reactions related to medication errors will be recorded in the study period and the rate calculated as number of cases divided by number of treatment years. Exact 95% binomial confidence intervals for the calculated rate will be reported.

## Documents

### Study results

[Pharmedgen PASS summary\\_final.pdf](#) (24.84 KB)

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## 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

# Data characterisation

## **Data characterisation conducted**

Unknown