# Assessment of Oralair® use in real-life (EVORA)

First published: 13/05/2015

**Last updated:** 02/04/2024





# Administrative details

EU PAS number
EUPAS9358
Study ID
49935
DARWIN EU® study
No
Study countries
France

## **Study description**

Oralair® is a sublingual immunotherapy tablet indicated for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis with relevant clinical symptoms confirmed by positive skin test and or existence of pollen

specific IgE antibodies for any of the five grass species contained in this drug. Oralair® is approved for use in children (older than 5 years of age) and adults. The EVORA study was requested by the French authorities to assess the use of Oralair® in real-life in France. This study is a prospective cohort of 300 adults and 150 children who initiate Oralair® for the next pollen season with a follow-up until the end of the season and is conducted by allergy specialists.

#### **Study status**

**Finalised** 

## Research institutions and networks

## Institutions



## Contact details

## **Study institution contact**

Patrick Blin plateforme.bpe@u-bordeaux.fr

Study contact

plateforme.bpe@u-bordeaux.fr

## Primary lead investigator

Patrick Blin

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 20/12/2013

#### Study start date

Planned: 01/12/2014

Actual: 01/12/2014

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

Planned: 30/04/2016

Actual: 23/06/2016

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Stallergenes SA

# Regulatory

Was the study required by a regulatory body? Yes
Is the study required by a Risk Management Plan (RMP)?  Not applicable
Methodological aspects
Study type
Study type list
Study topic: Disease /health condition Human medicinal product
Study type: Non-interventional study
Scope of the study: Disease epidemiology Drug utilisation
Data collection methods:
Primary data collection  Main study objective:

To describe the prescription patterns of Oralair®: indication, dosage, date of drug initiation compared to pollen season, concomitant drugs including antihistamines, local corticosteroids, cromones, and decongestants

# Study Design

### Non-interventional study design

Cohort

# Study drug and medical condition

#### Study drug International non-proprietary name (INN) or common name

GRASS POLLEN ALLERGEN EXTRACT

#### **Anatomical Therapeutic Chemical (ATC) code**

(V01AA02) grass pollen grass pollen

#### Medical condition to be studied

Rhinitis allergic

# Population studied

#### Short description of the study population

Allergic rhinitis with or without conjunctivitis in children (older than 5 years of age) and adults treated with Oralair® in real-life in France.

#### Age groups

- Adolescents (12 to < 18 years)</li>
- Children (2 to < 12 years)
- Adults (18 to < 46 years)</li>
- Adults (46 to < 65 years)</li>
- Adults (65 to < 75 years)</li>
- Adults (75 to < 85 years)
- Adults (85 years and over)

#### **Special population of interest**

Other

#### Special population of interest, other

Patients with allergic rhinitis

#### **Estimated number of subjects**

450

# Study design details

#### Data analysis plan

Statistical analysis will be carried out by the Bordeaux pharmacoepi according to a documented and approved Statistical Analysis Plan (SAP). The SAP describes statistical analysis as foreseen at the time of planning study. Statistical analysis will be performed after database lock using SAS® software (SAS Institute, last version, North Carolina, USA). Statistical analysis will be conducted separately for children and for adults. Qualitative variables (binary or categorical) and ordinal variables will be described in terms of number and frequency. Quantitative variables will be described in terms of number, mean, standard deviation, median and extreme values. The 95% confidence interval

will be calculated for the relevant parameters.

## **Documents**

#### **Study publications**

Blin P, Demoly P, Drouet M, Falissard B, Lignot-Maleyran S, Maizi H, Lorrain S,...

# 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 stability**

**Check conformance** 

Unknown

# **Check logical consistency**

Unknown

# Data characterisation

#### **Data characterisation conducted**

No