# EVORA - Evaluation of Oralair® in real conditions of use

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## General

### Identification

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|---|---|
| Detailed name | Evaluation of Oralair® in real conditions of use |
| Sign or acronym | EVORA |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CCTIRS n°14.514 - CNIL n°914403 |

### General Aspects

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|---|---|
| Medical area | General practice<br>Otolaryngology or ENT<br>Pediatrics<br>Pneumology<br>Study of allergies |
| Pathology (details) | Allergic rhinitis with or without conjunctivitis with grass pollen |
| Health determinants | Lifestyle and behavior<br>Medicine |
| Keywords | Bordeaux PharmacoEpi Platform, Grass pollen, Adults and children, Prospective cohort, Allergic rhinitis with or without conjunctivitis, Oralair, Department of Medical Pharmacology |

### Scientific investigator(s) (Contact)

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## Collaborations

## Funding

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| Funding status | Private |
| Details | LABORATOIRE STALLERGENES |

## Governance of the database

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| Sponsor(s) or organisation(s) responsible | Universite de Bordeaux - Plateforme Bordeaux PharmacoEpi - Service de pharmacologie médicale - CIC Bordeaux CIC1401 |
| Organisation status | Public |
| Presence of scientific or steering committees | Yes |
| Labelling and database evaluation | Quality control of the data entered (internal control) |

## Additional contact

## Main features

| Type of database | |
|---|---|
| Type of database | Study databases |
| Study databases (details) | Cohort study |
| Database recruitment is carried out by an intermediary | An administrative base or a register |
| Base or register (detail) | List of health-care professionals qualified in allergology via CEGEDIM |
| Database recruitment is is made on the basis of: | Medication(s) taken |
| Database recruitment is carried out as part of an interventional study | No |
| Additional information regarding sample selection. | Patients (adults and children from 5 years of age) were prospectively included between November 2014 and February 2015 by participating physicians specialising in allergology. |
| **Database objective** | |
| Main objective | Describe the prescription details of Oralair®: indication, dosage, date of introduction of the treatment with respect to the pollen season, concomitant treatments, in particular antihistamines, local corticosteroids, cromones and decongestants. |
| Inclusion criteria | Patient initiating a treatment with Oralair® for the next pollen season,<br>Patient not previously treated with Oralair®.<br><br>Exclusion criteria:<br>Refusal to participate,<br>Patient not living in the area or expected to move during the study period,<br>Patient with a language barrier (unable to read the newsletter or complete self-questionnaires)<br>Patient participating in a therapeutic clinical trial |
| **Population type** | |
| Age | Childhood (6 to 13 years)<br>Adolescence (13 to 18 years)<br>Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years) |

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| | Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | Sick population |
| Pathology | X - Diseases of the respiratory system |
| Gender | Male<br>Woman |
| Geography area | National |
| Detail of the geography area | Physicians in either private and hospital practice or both with an allergology activity in France |
| **Data collection** | |
| **Dates** | |
| Date of first collection (YYYY or MM/YYYY) | 2014 |
| Date of last collection (YYYY or MM/YYYY) | 2015 |
| **Size of the database** | |
| Size of the database (number of individuals) | [500-1000[ individuals |
| Details of the number of individuals | 525 patients (311 adults and 214 children) |
| **Data** | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data<br>Declarative data<br>Biological data<br>Administrative data |
| Clinical data (detail) | Direct physical measures |
| Details of collected clinical data | General characteristics of the patient (sex, age, comorbidities, treatments) - Results of assays/tests and symptomatology of allergic rhinitis |
| Declarative data (detail) | Paper self-questionnaire<br>Phone interview |
| Details of collected declarative | Collection of the perception of the symptoms of |

| | |
|---|---|
| data | allergic rhinitis on quality of life before and after use of the treatment |
| Biological data (detail) | Specific IgE assay results for grass pollen |
| Administrative data (detail) | Surname, first name, phone number and e-mail address |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity<br>Health care consumption and services<br>Quality of life/health perception |
| Care consumption (detail) | Medical/paramedical consultation<br>Medicines consumption |
| Quality of life/perceived health (detail) | Treatment outcome score (positive or negative benefit) from self-evaluation questionnaires of the symptoms on quality-of-life completed by patients |

## Procedures

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| Data collection method | The study data is collected through standardised paper questionnaires completed by participating physicians and standardised self-questionnaires completed by patients. The data is then entered into a specific study database |
| Participant monitoring | Yes |
| Monitoring procedures | Monitoring by contact with the participant (mail, e-mail, telephone etc.)<br>Monitoring by contact with the referring doctor |
| Details on monitoring of participants | After the inclusion consultation, participating physicians were asked to complete an end-of-study questionnaire at the end of the pollen season (by September 2015) for each patient included and monitored. For patients not seen by physicians, the questionnaire was completed directly with the patient during a telephone interview conducted by the clinical research associates of the coordinating Centre. |
| Links to administrative sources | Yes |
| Linked administrative sources (detail) | The population included and monitored in the study was compared with the EGB population |

## Promotion and access

### Promotion

| Access | |
|---|---|
| Presence of document that lists variables and coding procedures | Yes |
| Terms of data access (charter for data provision, format of data, availability delay) | Ownership of and access to the study data were the subject of an agreement between the Université de Bordeaux and the laboratory. The terms of access to the database must be established by a request to the study's scientific advisory board. |
| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |