An observational study of ORALAIR® (Grass pollen allergen extract from: Cocksfoot, Sweet Vernal, Rye Grass, Meadow Grass, Timothy) tablet for sublingual use in children 5 to 9 years of age with grass-pollen-induced allergic rhinitis (SL74.14)

First published: 22/12/2014

Last updated: 09/07/2018

Study Finalised

Administrative details

EU PAS number

EUPAS8104

Study ID

24770

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] France
- [ ] Germany

Study description

Safety and tolerability of ORALAIR in children 5 to 9 years of age during the first 30 days of treatment

Study status

Finalised

Research institutions and networks

Institutions

Stallergenes

First published: 01/02/2024

Last updated: 01/02/2024

Institution

NA,retrospective database analysis

Multiple centres: 103 centres are involved in the study

Contact details

Study institution contact

Global Clinical Development Stallergenes SAS

gcd_study@stallergenes.com

Study contact

gcd_study@stallergenes.com

Primary lead investigator

Global Clinical Development Stallergenes SAS

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/10/2014

Actual: 29/10/2014

Study start date

Planned: 01/12/2014

Actual: 19/01/2015

Data analysis start date

Planned: 01/09/2017

Actual: 03/07/2017

Date of final study report

Planned: 31/12/2017

Actual: 15/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Stallergenes SAS

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study is to further describe the safety and tolerability of ORALAIR tablets for sublingual use in children 5 to 9 years of age with grass-pollen-induced allergic rhinitis with or without conjunctivitis.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V01AA02) grass pollen

grass pollen

Medical condition to be studied

Seasonal allergy

Population studied

Short description of the study population

Allergen immunotherapy naive male or female outpatients aged 5 to 9 years (inclusive) prescribed with Oralair®.

Age groups

Children (2 to < 12 years)

Special population of interest

Other

Special population of interest, other

Seasonal allergy patients

Estimated number of subjects

300

Study design details

Outcomes

All adverse events that started on or after the day the first dose of ORALAIR.

Data analysis plan

An overall summary of all AEs, including the number of events and the number and percentage of patients with AEs will be provided. AEs will be summarized by Medical Dictionary for Regulatory Activities (MedDRA) System Organ Class (SOC) and Preferred Term (PT). Additional tables will summarize AEs by severity grade and relationship to the treatment. Tables summarizing Serious Adverse Events and AEs leading to study withdrawal will also be provided. Detailed patient listings of all AEs will be provided including the onset date and time, the duration of the reaction and the time interval since previous dose of Oralair

intake.

Documents

Study results

SL74.14_CSR synopsis_V1.0_15Dec2017.pdf(142.37 KB)

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 conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No