# Study of the safety and tolerability of ORYLMYTE in routine practice in adolescents and adults (VORAN)

**First published:** 10/11/2021

**Last updated:** 23/04/2024

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS44205

**Study ID**

44429

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

Prospective, open-label, multicentre, non-interventional, longitudinal Post Authorization Safety Study (PASS) in adolescents (12-17 years) and adults to further describe the safety and tolerability of ORYLMYTE

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Stallergenes

**First published:** 01/02/2024

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**Institution**

# Contact details

**Study institution contact**

Medical Department Stallergenes GmbH
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**Study contact**

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**Primary lead investigator**

Medical Department Stallergenes GmbH

Primary lead investigator

# Study timelines

**Date when funding contract was signed**
Planned: 28/06/2021

Actual: 28/06/2021

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**Study start date**
Planned: 15/10/2021

Actual: 12/11/2021

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**Data analysis start date**
Planned: 15/01/2024

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**Date of final study report**
Planned: 15/10/2024

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Stallergenes GmbH

# Regulatory

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

No

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

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Main study objective:**

To further describe the safety and tolerability of ORYLMYTE® during the first treatment year in adolescents and adults suffering from moderate to severe House Dust Mites (HDM)-induced allergic rhinitis (AR) or allergic rhinoconjunctivitis (ARC), with or without controlled asthma.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(V01AA03) house dust mites

house dust mites

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**Medical condition to be studied**

Rhinitis allergic

Conjunctivitis allergic

Perennial allergy

# Population studied

**Age groups**

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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**Estimated number of subjects**

1.500

# Study design details

**Outcomes**

All adverse events (AEs) having occurred from the first intake of ORYLMYTE® until the end of the study. Effect of the treatment on the allergic symptoms and on the use of symptomatic medication, patient’s well-being, effect of the treatment on sleep, pharmacoeconomic impact of the treatment (in terms of absenteeism).

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**Data analysis plan**

AE will be classified by Preferred Term (PT) and corresponding System Organ Class (SOC) using the current MedDRA terminology. Patients with AEs will be summarized as follows: - Patients with at least one Adverse Event (AE), at least one Adverse Drug Reaction (ADR, i.e. an event related to ORYLMYTE), at least one Serious Adverse Event (SAE), at least one Serious Adverse Drug Reaction (SADR) - Patients with at least one ADR leading to definitive discontinuation of ORYLMYTE Numbers and percentages of patients with at least one reported AE will be tabulated by MedDRA SOC and PT as follows: - All AEs, SAEs, ADRs, SADRs - All ADRs by intensity, severe ADRs, ADRs leading to definitive discontinuation of ORYLMYTE

# 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