# Actual conditions of use of OraVerse® in patients among resident dentists throughout Germany (OraDUS)

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# Administrative details

**Study description** 

| EU PAS number    |  |
|------------------|--|
| EUPAS11650       |  |
| Study ID         |  |
| 11651            |  |
| DARWIN EU® study |  |
| No               |  |
| Study countries  |  |
| Germany          |  |
|                  |  |

A retrospective, observational, cross-sectional drug utilisation survey among resident dentists throughout Germany to investigate the conditions of use of OraVerse® after local anesthetic procedures in daily routine clinical practice, and to investigate the use of OraVerse® according to labelling.

#### **Study status**

Finalised

## Research institutions and networks

## **Institutions**

## Sanofi

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Institution

Clinical Study Unit and Winicker Norimed

## Contact details

**Study institution contact** 

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## **Primary lead investigator**

## Monika Daubländer

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Actual: 09/04/2014

#### Study start date

Planned: 01/05/2014

Actual: 10/04/2014

## **Date of final study report**

Planned: 01/01/2015

Actual: 16/12/2014

# Sources of funding

Pharmaceutical company and other private sector

# More details on funding

Sanofi-Aventis Deutschland GmbH

# Study protocol

A-301410\_ORADUS\_NIS\_Protocol\_LR.pdf.PDF (1.5 MB)

# Regulatory

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

No

# Methodological aspects

# Study type

# Study type list

## **Study topic:**

Human medicinal product

#### Study type:

Non-interventional study

## Scope of the study:

Drug utilisation

#### **Data collection methods:**

Primary data collection

#### Main study objective:

The outcomes of interest will be the conditions of use of treatment. The primary outcomes will be the incidence of patients who "comply" / "not comply" with the recommendations in the SmPC regarding the following points: Patient age class Body weight class Type of dental intervention Local anesthetic used (product and dose) Dose of OraVerse® used

# Study drug and medical condition

#### Name of medicine, other

OraVerse

# Population studied

#### Short description of the study population

Patients treated with OraVerse® after local anesthetic procedure (with a local anesthetic containing a vasoconstrictor) by dentists within the last 3 months before contract signing.

#### 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)

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

523

# Study design details

#### **Outcomes**

The primary outcome was the proportion of patients that 'comply' with the conditions of use of OraVerse® according to the specifications in the Summary of Product Characteristics (SmPC). Dental interventions considered

routine interventions were specified by the Company after discussion with the clinical expert.

#### Data analysis plan

Data collection: Dentists reported on conditions of use of OraVerse® from individual patients on 'per-patient' documentation forms. Safety data collection: retrospective detection of safety signals. Data management, review, validation: data collection was completely anonymous as requested by the authorities. Therefore, no backtracking was possible and no data quality control at site level was performed. Summary of statistical methods used: Data management and statistical analysis were performed using SAS, version 9.2. All study data were analyzed in an exploratory fashion by means of descriptive statistics. Compliance analysis: For the analysis of the primary outcome, the proportions of compliance and of non-compliance with the specifications in the SmPC were calculated for all compliance variables separately.

## **Documents**

#### Study results

Oradus\_StudyReport\_incl\_Appendices\_V3.3\_20141216\_incl approval.pdf (1.97 MB)

# 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

Product registry, registry number: PHENLL07113

# 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