

# Observational Post-Authorisation Study of Oxervate® (Cenegermin 20 µg/ml) eye drops in the treatment of adult patients with moderate or severe Neurotrophic Keratopathy. (DEV0118)

**First published:** 15/11/2019

**Last updated:** 23/02/2022

Study

Finalised

## Administrative details

### EU PAS number

EUPAS32335

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### Study ID

45907

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### DARWIN EU® study

No

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### Study countries

 Italy

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## Study description

Oxervate® was approved for the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratopathy in adults by European Medicines Agency in 2017. The objective of this study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate or severe Neurotrophic Keratopathy to give insight on the utilization of this topical treatment in real-world clinical practice rather than strict conditions imposed by a formal clinical trial. This long-term product registry aims to consolidate existing data sources on patients diagnosed with moderate or severe Neurotrophic Keratopathy exposed to Oxervate® in qualified ophthalmological centers from participating countries in EU.

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## Study status

Finalised

## Research institutions and networks

### Institutions

Multiple centres: 7 centres are involved in the study

## Contact details

### Study institution contact

Flavio Mantelli [flavio.mantelli@dompe.com](mailto:flavio.mantelli@dompe.com)

**Study contact**

[flavio.mantelli@dompe.com](mailto:flavio.mantelli@dompe.com)

**Primary lead investigator**

Alessandro Lambiase

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Actual: 30/09/2018

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**Study start date**

Actual: 17/06/2019

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**Date of final study report**

Planned: 31/12/2021

Actual: 06/09/2021

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Dompé farmaceutici S.p.A.

## Regulatory

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

No

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Real World Evidence

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this observational study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate and severe Neurotrophic Keratopathy to give insight on the utilization of this topical treatment in real-world clinical practice rather than strict conditions imposed by a formal clinical trial.

## Study Design

### **Non-interventional study design**

Other

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### **Non-interventional study design, other**

Multicentre, prospective, observational study/registry, Post-Authorisation Study

## Study drug and medical condition

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

CENEGERMIN

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### **Medical condition to be studied**

Neurotrophic keratopathy

## Population studied

### **Short description of the study population**

Adult patients diagnosed with moderate or severe NK were planned to be enrolled at approximately 30 sites in selected European countries (Italy,

Germany, Spain,  
France).

#### Inclusion criteria

The following were the requirements for entry into the study:

1. Male or female 18 years of age or older.
2. Diagnosis of moderate (persistent epithelial defect, PED) or severe (corneal ulcer) neurotrophic keratopathy by the Investigator.
3. The prescribing decision has been made to initiate treatment with Oxervate®.
4. Written documentation of informed consent has been obtained in accordance with the relevant Country and local privacy requirements, as applicable.

#### Exclusion criteria

The following were the criteria for exclusion from participating in the study:

1. Patients who were contraindicated to Oxervate® treatment as per the European SmPC.
  2. Concurrent participation in a clinical trial that dictated treatment or use of an investigational drug
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#### **Age groups**

- 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)
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#### **Special population of interest**

Other

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## **Special population of interest, other**

Neurotrophic keratopathy patients

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## **Estimated number of subjects**

250

# Study design details

## **Outcomes**

The objective of this study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate or severe Neurotrophic Keratopathy (NK).

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## **Data analysis plan**

Summary descriptive statistics and rate calculation will be presented analyzing demographic data on patients (age, sex, ethnicity, race), prior disease data (disease course time of disease onset, date of diagnosis, symptoms at onset, past disease activity and stage), referral flow (patient from general practitioner/ophthalmologist, other hospital, other private clinic, Investigator, Emergency Room of the same center), treatment data (symptomatic therapies, previous and current therapies including Oxervate®, other therapies for other conditions), relevant clinical tests and clinical events of medical interest. The safety population which includes any patient who receives at least one treatment of Oxervate® regardless of the length of follow-up. Treatment exposure will be summarized in terms of compliance to treatment.

# Documents

## **Study results**

[DEV0118 Clinical Research Report Final Version 1.0\\_06092021.pdf](#) (1.74 MB)

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Data management

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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No