

# Effectiveness and tolerability of the THC:CBD oromucosal spray as add-on measure in patients with severe chronic pain: analysis of 12-week open-label real-world data provided by the German Pain e-Registry (ETORO-PAIN)

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Study

Planned

## Administrative details

### EU PAS number

EUPAS25799

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### Study ID

25800

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### DARWIN EU® study

No

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### Study countries

☐ Germany

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### Study description

Cross-sectional retrospective analysis of anonymized real-world data provided by the German Pain e-Registry on the effectiveness, safety and tolerability of an oromucosal spray containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD), given as add-on treatment in patients with severe chronic pain (SCP) in routine clinical practice.

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### Study status

Planned

## Research institutions and networks

### Institutions

[Institute for Neurological Sciences \(IFNAP\)](#)

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Institution

## Contact details

### Study institution contact

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Study contact

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**Primary lead investigator**

Michael Ueberall

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/11/2017

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**Study start date**

Planned: 10/03/2017

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**Data analysis start date**

Planned: 29/01/2018

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**Date of interim report, if expected**

Planned: 08/03/2018

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**Date of final study report**

Planned: 15/06/2018

## Sources of funding

- Pharmaceutical company and other private sector
- Other

## More details on funding

## 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 type:**

Non-interventional study

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#### **Scope of the study:**

Drug utilisation

Effectiveness study (incl. comparative)

#### **Main study objective:**

Main objective of this analysis is to gain further insight into their differential effects and the benefit-risk profile (BRP) of THC:CBD oromucosal spray given add-on to patients with elsewhere refractory severe chronic pain under real life conditions.

## Study Design

## Non-interventional study design

Cohort

Cross-sectional

## Study drug and medical condition

### Medicinal product name, other

Sativex

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### Medical condition to be studied

Musculoskeletal pain

## Population studied

### 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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### Estimated number of subjects

800

## Study design details

### Outcomes

Primary efficacy endpoint is an aggregated 9-factor symptom relief score (ASR-9) defined as a composite of nine efficacy parameters (at least 50% improvement of pain, pain-related disabilities in daily life, sleep, overall wellbeing, physical and mental quality-of-life, depression, anxiety and stress, each at end of observation vs. baseline). Safety endpoints is the spectrum of treatment emergent adverse reactions (TEAEs) and the proportion of related treatment discontinuations.

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### **Data analysis plan**

Exploratory analysis of anonymized 12-week routine/open-label data of the German Pain e-Registry (GPR) on adult SCP patients, in whom a treatment with THC:CBD has been initiated in compliance with the current German prescribing regulations between March 10th and December 31st, 2017. No formal sample size analysis will be performed. Data analyses will be performed for all registered patients who took at least one dose of study medication and who had at least one post-baseline/post-dose measure (modified intent-to-treat approach). Analyses will be performed for patient samples with nociceptive, mixed or neuropathic pain identified with the modified 7-dimensional patient-reported pain detect questionnaire (PDQ7) to gain best insight into the effectiveness of THC:CBD in different pain mechanisms.

## **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)**

Electronic healthcare records (EHR)

## 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