

# Drug utilisation study of Intuniv® (guanfacine extended release) in European Countries – A prescriber survey (Intuniv survey study Europe)

**First published:** 26/04/2017

**Last updated:** 11/11/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS18739

### Study ID

48514

### DARWIN EU® study

No

### Study countries

- Belgium
- Finland
- Ireland

Netherlands

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### Study description

This is a multinational, cross-sectional, non-interventional and anonymous survey to assess drug utilisation of Intuniv which is indicated for treatment of attention deficit hyperactivity disorder. The survey will be carried out among physicians who will be asked to provide de-identified patient data. The survey will be conducted through a web-questionnaire among prescribers of Intuniv® in four European countries (Belgium, Finland, Ireland, Netherlands). In other countries utilization of Intuniv will be assessed in a database analysis which is described in a separate protocol.

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### Study status

Finalised

## Research institutions and networks

### Institutions

#### Real World Solutions, IQVIA

Netherlands  
 United Kingdom (Northern Ireland)

**First published:** 28/04/2011

**Last updated:** 22/03/2024

**Institution**

**Other**

**ENCePP partner**

## Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Dorothea von Bredow

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 30/08/2016

Actual: 30/08/2016

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**Study start date**

Planned: 01/02/2019

Actual: 20/02/2019

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**Date of interim report, if expected**

Planned: 30/06/2019

Actual: 11/06/2019

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**Date of final study report**

Planned: 30/06/2022

Actual: 16/06/2023

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## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Takeda Pharmaceutical Company Limited

## Study protocol

[INTUNIV EU DUS\\_SURVEY Protocol v5.0\\_17Jul2018\\_redacted.pdf](#) (305.77 KB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**Main study objective:**

Overall: Drug utilization study with Intuniv® in European countries until 2021.

Results will be reported annually. Study objectives: 1. characterize patients, focussing on indications other than ADHD, children <6 years, adults 2. describe prescribing patterns of Intuniv® among physicians 3. assess compliance with indication, visits and measurements needed during the first year of treatment</6></6>

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Multinational, non-interventional and anonymous survey

## Study drug and medical condition

**Medicinal product name**

INTUNIV

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

GUANFACINE HYDROCHLORIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(C02AC02) guanfacine

guanfacine

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**Medical condition to be studied**

Attention deficit hyperactivity disorder

## Population studied

**Short description of the study population**

A survey of physicians prescribing Intuniv® for the treatment of attention deficit/hyperactivity disorder (ADHD) in Belgium, Finland, Ireland, and Netherlands from 2019 to 2022.

Inclusion criteria:

- Prescribers of Intuniv®, i.e. physicians who know and have prescribed the drug at least once during the previous 12 months (or, for the first report, since country specific launch) (paediatricians, psychiatrists, neurologists and GPs).

Exclusion criteria:

Inactive and retired physicians (when documented information is available to identify them) will be deleted from the contact lists before randomisation.

The following exclusion criteria will be checked at the beginning of the web questionnaire:

- Physicians who do not treat patients or who may have a conflict of interest (i.e. physicians employed by regulatory bodies or pharmaceutical industries).

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## **Age groups**

- Infants and toddlers (28 days – 23 months)
- 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)

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## **Special population of interest**

Other

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

Patients with attention deficit/hyperactivity disorder

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## **Estimated number of subjects**

1000

## **Study design details**

### **Data analysis plan**

Data analysis will be done descriptively as specified in the statistical analysis plan.

## **Documents**

## Study results

[Intuniv EU survey study redacted abstract final report.pdf \(3.69 MB\)](#)

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## 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

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### Data sources (types), other

Data will be collected within a survey conducted among a representative sample of physicians known to treat patients with ADHD. The survey will collect data from the following sources:

- physicians files (OneKey lists)
- information collected by a web questionnaire, including de-identified patient data.

## 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