

# Drug utilization study of mirabegron (Betmiga®) using real-world healthcare databases from the Netherlands, Spain, United Kingdom and Finland (Mirabegron DUS)

**First published:** 27/01/2017

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS15063

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### Study ID

29595

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### DARWIN EU® study

No


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### Study countries

 Finland

 Netherlands

 Spain

 United Kingdom

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## **Study description**

The mirabegron (Betmiga®) Summary of Product Characteristics (SmPC) states that the drug is contraindicated in patients with “Severe uncontrolled hypertension defined as systolic blood pressure  $\geq$ 180 mm Hg and/or diastolic blood pressure  $\geq$ 110 mm Hg”. In accordance and compliance with the European Medicines Agencies (EMA’s) Pharmacovigilance Risk Assessment Committee (PRAC) request, a Direct Healthcare Professional Communication (DHPC) letter was disseminated on 7 September 2015 as a risk minimization activity in 30 countries in EU. In line with the EMA CHMP guideline Module IX, an effectiveness check of this risk minimization activity was proposed by Astellas. A drug utilization study (DUS) on the use of mirabegron in the Netherlands, Spain, United Kingdom and Finland will be performed as a risk minimization effectiveness check measure. The objectives of the study are to assess the effectiveness of the Direct Healthcare Professional Communication (DHPC) letter as a risk minimization measure in the participating countries by quantifying the proportions of mirabegron initiators with documented severe uncontrolled hypertension (primary objective) and the frequency of blood pressure recordings at baseline and during mirabegron treatment, especially in hypertensive patients (secondary objective) before and after DHPC dissemination.

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## **Study status**

Finalised

## **Research institutions and networks**

### **Institutions**

## The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

 Netherlands

**First published:** 07/01/2022


**Last updated:** 19/12/2025

**Institution**

**Non-Pharmaceutical company**

**ENCePP partner**

## Clinical Practice Research Datalink (CPRD)

 United Kingdom

**First published:** 15/03/2010


**Last updated:** 17/01/2025


**Institution**

**Laboratory/Research/Testing facility**


**ENCePP partner**

## Global Database Studies, IQVIA

 Czechia

 Finland

 Germany

 Slovakia

 Spain

**First published:** 17/01/2011

**Last updated:** 31/07/2024

**Institution**

**Other**

**ENCePP partner**

# Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

 Spain

**First published:** 05/10/2012

**Last updated:** 23/05/2025

**Institution**

**Educational Institution**

**Laboratory/Research/Testing facility**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

[pharmo@pharmo.nl](mailto:pharmo@pharmo.nl)

### Primary lead investigator

Ron Herings

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 26/07/2016

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**Study start date**

Actual: 21/02/2017

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**Data analysis start date**

Actual: 17/03/2017

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**Date of final study report**

Actual: 11/07/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Astellas

## Study protocol

[178-pv-002-clp-en-final-v1-02.pdf](#) (1.34 MB)

[PHARMO-Study Protocol-Mirabegron DUS\\_v1.2.pdf](#) (1.39 MB)

## Regulatory

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

Yes

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

EU RMP category 3 (required)

## Methodological aspects

## Study type

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The objectives are to assess the effectiveness of the DHPC letter as a risk minimization measure by quantifying the proportions of mirabegron initiators with severe uncontrolled hypertension (primary objective) and the frequency of blood pressure recordings at baseline and during mirabegron treatment, especially in hypertensive patients (secondary objective) before and after DHPC dissemination.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(G04BD12) mirabegron

mirabegron

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

Hypertension

## Population studied

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

Mirabegron initiators during the years 2012-2016.

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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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### **Estimated number of subjects**

50000

## Study design details

### **Outcomes**

For the primary objective we will assess whether the proportions of mirabegron initiators with documented hypertension (severe uncontrolled hypertension but also controlled hypertension or non-severe uncontrolled hypertension) differ between the time periods before and after DHPC dissemination. For the

secondary objective we will assess whether the frequency of blood pressure recordings at initiation and during mirabegron treatment among initiators with documented hypertension at index date differ between the time periods before and after DHPC dissemination.

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### **Data analysis plan**

The DHCP letter was disseminated on 7 September 2015. The analysis pre- and post dissemination will take this date as the intervention date. Besides a pre- and post dissemination analysis, incremental changes over time will be assessed using the aggregated data per quarter (January-March, April-June, July-September and October-December). To estimate incremental changes in response to the DHPC letter in the proportion of mirabegron initiators with normal blood pressure, controlled hypertension, non-severe uncontrolled hypertension and severe uncontrolled hypertension at index date (primary objective), an interrupted time series approach will be applied on the respective proportions in each quarter. The frequency of blood pressure recordings will be assessed before initiation of and during mirabegron treatment (see section 9.3.4). Blood pressure recordings at or before index date (up to 6 months) will be reported separately from the recordings during treatment.

## Documents

### **Study results**

[178-pv-002-clgr-disc01-en-final-04.pdf](#) (111.31 KB)

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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 source(s)

Clinical Practice Research Datalink

The Information System for Research in Primary Care (SIDIAP)

PHARMO Data Network

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### Data sources (types), other

The Finnish data sources include the e-Prescription Register, Care Register for Health Care, Register of Primary Health Care Visits, Population Register Centre and Causes of Death Registry of Finland and electronic medical record databases of city of Helsinki, Vantaa and Espoo.

## 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**

Unknown