

# Drug utilization study of cyproterone/ethinylestradiol (Diane®-35 and generics) in the Netherlands, UK and Italy

**First published:** 23/01/2015

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS8412

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### Study ID

31117

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### DARWIN EU® study

No

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### Study countries

 Italy

 Netherlands

 Spain

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## Study description

The study objectives are to characterize new users of Cyproterone Acetate / Ethinylestradiol (CPA/EE) in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the Netherlands (PHARMO) and Italy (HSD).

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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**

#### Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

 Spain

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

**Last updated:** 15/02/2024

**Institution**

**Not-for-profit**

**ENCePP partner**

Italy HIS: The Health Search institute

## Networks

PHARMO: Database Network Netherlands

## Contact details

### Study institution contact

CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer  
HealthCare AG clinical-trials-contact@bayerhealthcare.com

**Study contact**

[clinical-trials-contact@bayerhealthcare.com](mailto:clinical-trials-contact@bayerhealthcare.com)

### Primary lead investigator

CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer  
HealthCare AG

**Primary lead investigator**

# Study timelines

## **Date when funding contract was signed**

Actual: 01/12/2014

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## **Study start date**

Planned: 01/02/2015

Actual: 01/05/2015

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## **Date of final study report**

Planned: 30/01/2016

Actual: 31/03/2016

# Sources of funding

- Pharmaceutical company and other private sector

# More details on funding

Bayer

# Study protocol

[17660\\_Study Protocol DUS Diane\\_2014-09-12.pdf](#) (523.32 KB)

[17660\\_02\\_Protocol\\_V7.0\\_2017\\_extension study.pdf](#) (3.21 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 1 (imposed as condition of marketing authorisation)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

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:**

Secondary use of data

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**Main study objective:**

Characterization of new users of Cyproterone Acetate / Ethinylestradiol CPA/EE in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the NL

(PHARMO) and Italy (HSD).

## Study Design

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

Cohort

## Study drug and medical condition

### **Anatomical Therapeutic Chemical (ATC) code**

(G03HB) Antiandrogens and estrogens

Antiandrogens and estrogens

## Population studied

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

New Cyproterone Acetate / Ethinylestradiol (CPA/EE) users in 2011 and 2012.

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### **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
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### **Estimated number of subjects**

10000

## Study design details

## Outcomes

1. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Acne  
2. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Hirsutism  
3. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of other Hyperandrogenic Conditions (e.g. androgenic alopecia, seborrhea, polycystic ovary syndrome),  
1. Determination of previous acne treatments (prescription drugs only) of Diane-35 (or generics) users with a previous diagnosis of acne.  
2. Proportion (%) of new Diane-35 (or generics) users, who have concomitant prescriptions of other combined oral contraceptives

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## Data analysis plan

Patient, treatment and diagnosis characteristics will be reported descriptively. Categorical data will be presented as counts (n) and proportions (%). Continuous data will be presented as means with standard deviation (SD) and as medians with inter quartile range (IQR) when appropriate. Results will be presented for the 2011/2012 users together and stratified by year of diagnosis.

## Documents

### Study results

[17660\\_EU-PAS\\_Abstract.pdf](#) (59.26 KB)

[17660\\_Study Report DUS Diane - final.pdf](#) (727.15 KB)

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### Study report

[17660\\_04\\_Report.pdf](#) (2.12 MB)

[17660\\_04\\_Report extension.pdf](#) (4.03 MB)

[17660\\_04\\_Report\\_1\\_interim.pdf](#) (727.05 KB)

### Study, other information

[17660\\_04\\_Report.pdf](#) (2.12 MB)

[17660\\_04\\_Report\\_1\\_interim.pdf](#) (727.05 KB)

## 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)

THIN® (The Health Improvement Network®)

PHARMO Data Network

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### Data source(s), other

HSD Italy

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### Data sources (types)

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

[Drug dispensing/prescription data](#)

[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