# Drug Utilisation Study of conjugated oestrogens/bazedoxifene (CE/BZA) in the European Union (EU)

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### Administrative details

#### **EU PAS number**

EUPAS11604

#### **Study ID**

35301

#### DARWIN EU® study

No

#### **Study countries**

Belgium

\_\_\_\_ Finland

France

Germany

Italy	
Netherlands	
Spain	
Sweden	
United Kingdom	

### **Study description**

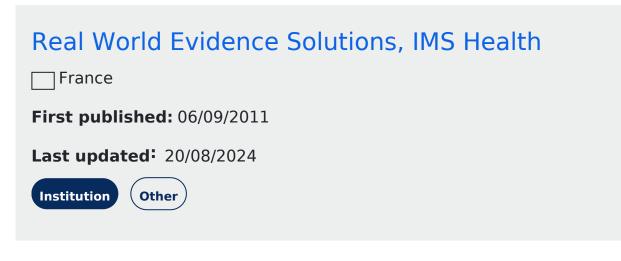
Describe baseline characteristics and utilisation patterns of EU patients initiating Duavive or oestrogen + progestin (E+P) combination hormone replacement therapy (HRT), in all EU countries where CE/BZA is commercially available in 2016-2017.

### Study status

Finalised

# Research institutions and networks

### Institutions



# Contact details

### Study institution contact Vera Frajzyngier vera.frajzyngier@pfizer.com

Study contact

vera.frajzyngier@pfizer.com

Primary lead investigator Vera Frajzyngier

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 24/04/2015 Actual: 24/04/2015

### Study start date

Planned: 22/10/2017 Actual: 22/10/2017

### Data analysis start date

Planned: 30/09/2017

### Date of interim report, if expected

Planned: 31/03/2018

### Date of final study report

Planned: 31/03/2020 Actual: 31/03/2020

## Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Pfizer, Inc.

# Study protocol

B2311061\_Duavive EU DUS FINAL Protocol CHMP ENDORSED OCT2015.pdf (917.89 KB)

b2311061 protocol amendment.pdf(2.43 MB)

### Regulatory

Was the study required by a regulatory body? Yes

Is the study required by a Risk Management Plan (RMP)? EU RMP category 3 (required)

### Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product Disease /health condition

#### Study type:

Non-interventional study

### Scope of the study: Drug utilisation

#### Data collection methods:

Secondary use of data

#### Main study objective:

The overall aim of this drug utilization study (DUS) is to describe the baseline characteristics and utilization patterns of EU patients initiating either Duavive or oestrogen + progestin hormone replacement therapy (E+P HRT).

## Study Design

#### Non-interventional study design

**Cross-sectional** 

## Study drug and medical condition

## Name of medicine

DUAVIVE

#### Medical condition to be studied

Menopausal symptoms

## Population studied

### Short description of the study population

Study subjects are all patients identified in the respective databases with at least one prescription for Duavive or E+P HRT during the defined study period. Patients must meet both of the following inclusion criteria to be eligible for this study:

1. All patients identified in the respective databases who have received at least one prescription for Duavive or E+P HRT during the 3 years following the first EU launch of Duavive will be included.

2. Patients need to be enrolled in the data source for at least 12 months prior to their earliest prescription of either Duavive or an (E+P) HRT comparator.

Patients with less than 12 months of database enrolment prior to their index prescription will be excluded.

#### Age groups

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)

### Estimated number of subjects

999

## Study design details

#### Data analysis plan

Among Duavive or E+P HRT users, analyses will be descriptive in nature, performed annually for 3 years, and use counts and percentages for categorical variables and means ±with standard deviations for continuous variables. Data from each EU country will be analyzed separately, and may be pooled when feasible, and results will be compared descriptively across countries. Once multiple years of data are available, trends over time will also be reported. The demographics (age, body mass index BMI) and clinical characteristics (comorbidities, concomitant medications, medical and drug history) of patients identified to have received a Duavive or E+P HRT prescription will be summarized from their 12 month period prior to treatment initiation (pre-index) and compared. The proportions of Duavive patients with possible off-label use will be described.

### Documents

#### **Study results**

b2311061-EU DUS\_smaller.pdf(1.73 MB)

### Study, other information

Annex 1\_Duavive EU DUS\_FINAL CHMP ENDORSED OCT2015.pdf(731.74 KB)

### Data management

Data sources

### Data source(s)

THIN® (The Health Improvement Network®) Sweden National Prescribed Drugs Register / Läkemedelsregistret Longitudinal Patient Data - France Longitudinal Patient Data Spain - OMOP IQVIA Longitudinal Patient Data - Belgium

### Data source(s), other

Longitudinal Prescription Data - Netherlands

### Data sources (types)

Administrative healthcare records (e.g., claims) Drug dispensing/prescription data

### Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

#### **Check conformance**

Unknown

#### **Check completeness**

Unknown

### Check stability

Unknown

### Check logical consistency

Unknown

# Data characterisation

### Data characterisation conducted

No