# PRJ2215: Assessment of Bupropion Misuse/Abuse 2004-2011 (201235)

**First published:** 17/01/2014

**Last updated:** 24/05/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS5568

**Study ID**

48174

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

The objective of this study is to examine the degree of misuse and abuse of bupropion using the Drug Abuse Warning Network Database. Objectives are as follows: 1. To examine the number of bupropion reports over time within the

DAWN database and to draw a comparison against the number of all DAWN reports for prescription drugs. 2. To examine the number of reports for bupropion, stratified by demographics, route of administration, and disposition of the patient.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### GlaxoSmithKline (GSK)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

# Contact details

**Study institution contact**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Pharma.CDR@gsk.com

**Study contact**

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**Primary lead investigator**

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Planned: 03/12/2013

Actual: 03/12/2013

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**Study start date**
Planned: 03/12/2013

Actual: 22/11/2013

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**Data analysis start date**
Planned: 03/12/2013

Actual: 03/12/2013

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**Date of final study report**
Planned: 31/03/2014

Actual: 16/06/2014

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

GlaxoSmithKline

# Study protocol

epi prj2215-protocol-redact.pdf (341.3 KB)

# Regulatory

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

No

**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

**Study type:**

Non-interventional study

**Scope of the study:**

Other

**If ‘other’, further details on the scope of the study**

Assessment of bupropion abuse potential

**Data collection methods:**

Primary data collection

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**Main study objective:**

1. To examine the number of bupropion reports over time within the DAWN databse and to describe the number of all DAWN reports for prescription drugs. This is analogous to the disproportionality analysis conducted within GCSP for the evaluation of safety signals.2. To examine the number of reports for bupropion, stratified by demographics, route of administration, and disposition of the patient

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective analysis of surveillance data reported in DAWN between 2004 and 2011.

## Study drug and medical condition

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

BUPROPION

## Population studied

**Short description of the study population**

The study population includes patients of all ages presenting to emergency departments for drug-related causes. The DAWN visit eligibility criteria are intended to be broad and inclusive and to have few exceptions. They take into account the fact that documentation in medical records varies in clarity and completeness across hospitals and among clinicians within hospitals. The criteria are designed to minimize the potential for DAWN Reporter judgments that could cause data to vary systematically and unexpectedly across different data collectors and hospitals. In addition, the criteria allow for the capture of a diverse set of drug-related visits that can be aggregated or disaggregated to serve a variety of analytical purposes and the interests of multiple audiences. There are a few clearly delineated exceptions to the DAWN eligibility criteria. An ED visit is not a DAWN visit if

- there is no evidence of recent drug use;
- the patient left the ED without being treated;
- the patient consumed a nonpharmaceutical substance but did not inhale it;
- the patient has a history of drug use but no recent use;
- alcohol is the only substance involved, and the patient is an adult (aged 21 or older);
- all the drugs mentioned in the ED record are not related to the ED visit (e.g., list of current medications);
- drugs identified in toxicology testing are not related to the visit, and the medical record does not contain any additional drug-related information that would make
the visit a DAWN case; or
- the patient is being treated as a consequence of undermedication (i.e., taking too little of a drug).

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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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**Estimated number of subjects**

0

## Study design details

**Data analysis plan**

Data on all reports of prescription drug misuse and abuse will be captured using the DAWN data sets from years 2004 to 2011, examined by year individually. Data on all reports of bupropion misuse and abuse will be captured using the same data. These data will include reports of bupropion without mention of any other drug. However, such reports will also be analysed as a separate category. Percent change will be evaluated for each year, as compared to the previous year. For each year in the study period, 2004-2011, a distribution of patient characteristics as well as case type and patient disposition will be captured in tables. These tables will note the number of patients in the DAWN dataset (unweighted) as well as weighted N and weighted percentages of all the bupropion reports.

## Documents

**Study results**

gsk-PRJ2215-clinical-study-report-redact.pdf (596.7 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 sources (types)**

Spontaneous reports of suspected adverse drug reactions

## 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