Prescriber and Pharmacist Understanding of the Risk of Urinary Retention with POTIGA (116490)

First published: 12/11/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS4851

Study ID

40745

DARWIN EU® study

No

Study countries

United States

Study description

As part of a post-marketing commitment, GSK will conduct a survey of prescribers’ and pharmacists’ understanding of the risk of urinary retention with retigabine products. This is to address the effectiveness of the Risk Evaluation and Mitigation Strategy (REMS) as outlined in the REMS approved by the FDA on 10th June 2011. The objectives of this survey are to assess prescribers’ and pharmacists’ understanding of the risk of urinary retention and the symptoms of acute urinary retention potentially associated with retigabine use as evaluated by a survey instrument. This is a cross-sectional study of approximately 200 physicians (e.g. neurologists/epileptologists/neurosurgeons) who have prescribed retigabine at least once in the last 12 months, and 200 pharmacists who have dispensed an anti-epileptic drug (AED) at least once in the last 3 months. The primary outcome of the survey is the proportion of physicians and pharmacists providing correct responses to a series of questions concerning the risk of urinary retention and the symptoms of acute urinary retention that may be associated with retigabine. The risks captured will be those described in the retigabine Dear Healthcare Provider (DHCP) letters, specifically risks of urinary retention. POTIGA is a trademark of Valeant Pharmaceuticals North America LLC, used by GlaxoSmithKline under license.

Study status

Finalised

Contact details

Study institution contact

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

Study contact

Pharma.CDR@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/02/2012

Actual: 14/02/2012

Study start date

Planned: 31/03/2013

Actual: 25/02/2013

Date of final study report

Planned: 12/10/2014

Actual: 28/05/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline LLC

Study protocol

Prot-Amend2-STD-WEUKBRE5993-P_116490_LI_Redacted.pdf (452.27 KB)

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The objectives of this survey are to assess prescribers’ and pharmacists’ understanding of the risk of urinary retention and the symptoms of acute urinary retention potentially associated with retigabine use as evaluated by a

survey instrument.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Prospective study, observational survey

Study drug and medical condition

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

RETIGABINE

Additional medical condition(s)

Epilepsy- Adjunctive treatment of drug-resistant partial onset seizures, with or without secondary generalisation, in patients with epilepsy where other appropriate drug combinations have proved inadequate or have not been tolerated

Population studied

Short description of the study population

Physicians and pharmacists were recruited from a demographically representative population who prescribe POTIGA and dispense POTIGA.

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)

Estimated number of subjects

0

Study design details

Outcomes

The proportion of physicians and pharmacists providing correct responses to a series of questions concerning the risk of urinary retention and the symptoms of acute urinary retention that may be associated with retigabine.

Data analysis plan

The population for analysis will comprise all physicians and pharmacists recruited into the study, meeting eligibility criteria as assessed in the survey screener, and completing the survey.The primary outcome is the proportion of HCPs answering each question of understanding of the risks associated with retigabine correctly. Point estimates for the proportion with correct responses, and associated 95% confidence intervals, will be calculated for each question about the awareness of risks of retigabine. In the case of multiple choice questions, the number and proportion of subjects reporting each response will also be provided.GSK considers a proportion (%) of correct responses of at least 80% for each individual question to represent sufficient subject understanding of the risks associated with retigabine.

Documents

Study results

gsk-116490-clinical-study-report-redact.pdf (1.36 MB)

WWE116490_final_report_Concentrics.pdf (146.02 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)

Drug claims information system

Data sources (types)

Other

Data sources (types), other

Prospective survey to collect prescriber and pharmacist responses

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