EDURANT / EVIPLERA Health Care Professional Survey (HCP survey on RPV)

First published: 07/02/2014

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Study Finalised

Administrative details

EU PAS number

EUPAS5565

Study ID

20230

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Belgium
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Netherlands

☐ Norway

☐ Sweden

☐ United Kingdom

Study description

The current summaries of product characteristics (SmPCs) state that EDURANT (rilpivirine) must be administered with a meal and EVIPLERA (emtricitabine/rilpivirine/tenofovir disoproxil fumarate) must be administered with food. Adherence to these instructions is important to ensure that adequate rilpivirine levels are maintained in order to optimise a patient's response to rilpivirine treatment.There is a need to attest that patients are being properly instructed to take EDURANT and EVIPLERA with a meal / with food as part of the therapeutic advice they receive from a health care professional (HCP). To address this, a survey is to be undertaken to establish current prescribing practices and instructions given to patients when a HCP prescribes / dispenses / instructs on the use of EDURANT or EVIPLERA. This will enable an understanding of the effectiveness of the current prescribing conditions (SmPC instructions and HCP instructions) with regards to the intake of the products with food / with a meal. The survey is to be developed and conducted by Ipsos Healthcare (a division of Ipsos MORI), who are an independent research agency conducting the survey on behalf of Janssen-Cilag International NV and Gilead Sciences International Ltd.

Study status

Finalised

Research institutions and networks

Institutions

IPSOS Healthcare

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Darren GRAINGER

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/04/2013

Actual: 24/06/2013

Study start date

Planned: 06/01/2014

Actual: 10/01/2014

Date of final study report

Planned: 28/11/2014

Actual: 16/10/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag International NV

Study protocol

IPSOS proposal.pdf(398.29 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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The objective of the survey is to gain an understanding of the effectiveness of the current prescribing conditions in minimising the risk of virological failure and development of resistance associated with taking EDURANT or EVIPLERA without food.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

On-line survey

Study drug and medical condition

Name of medicine

EVIPLERA

Name of medicine, other

EDURANT

Medical condition to be studied

HIV infection

Population studied

Short description of the study population

HIV treating Health Care Professional who must see at least 10 HIV patients per month, have recently prescribed/dispensed/instructed patients to take Edurant and/or Eviplera within the last 3 months and will be the person most involved, within their current work setting, in instructing patients on how to take their HIV medication.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

289

Study design details

Outcomes

To consider the current prescribing conditions sufficient to minimise the risk of patients taking EDURANT / EVIPLERA without a meal / food, at least 80% of HCPs will correctly identify the instructions for these products relating to food intake (Q2 in on-line survey). Additionally, it will be necessary for at least 80% of patients, on average, to be given the instruction that EDURANT must be taken with a meal / EVIPLERA must be taken with food / a meal when prescribed the treatment for the first time.

Data analysis plan

Upon completion of the survey by the required sample respondents (N=289), data collected during the course of the survey will be aggregated and tabulated. All questions will be analysed individually as well as cross-tabulated with other survey questions to allow for more in-depth analysis. Most commonly anticipated cross-tabulations will include HCP type and prescription level (high versus medium versus low). Answers to open-ended questions will be grouped together and assigned to aggregated answer codes for the purposes of analysis and reporting.For each question, the base of the respondents answering it will bepresented. All results included will be significance tested (95% CI) and where significant differences are observed these will be highlighted.

Documents

Study results

EDURANT EVIPLERA PASS Report (HCP Survey)_EDMS-ERI-88865066_1.0.pdf (1.25 MB)

Study, other information

IPSOS questionnaire.pdf(172.02 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Ipsos' panel of physicians for relevant markets

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

Unknown