TAK-669-4018: A Survey Among Patients, Caregivers and Home Infusion Nurses Based in the European Union to Assess Their Awareness and Understanding of Educational Materials Supporting VPRIV® Infusion at Home

First published: 20/12/2022

Last updated: 31/03/2026

Study Planned

Administrative details

EU PAS number

EUPAS49598

Study ID

49599

DARWIN EU® study

No

Study countries

Austria
Belgium
Denmark
Finland
France
Germany
Ireland
Italy
Netherlands
Spain

Study description

The main purpose of this survey is to determine participants', caregivers', and nurses' understanding and use of educational material (EM) on VPRIV home treatment. EM includes an infusion diary and guide and an emergency plan related to VPRIV infusion given at home for Gaucher disease. The survey is conducted in European countries. Data will be collected directly from participants, caregivers, and nurses in form of a questionnaire, electronic or paper.

Study status

Planned

Research institutions and networks

Institutions

Takeda

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Contact Takeda TrialDisclosures@takeda.com

Study contact

TrialDisclosures@takeda.com

Primary lead investigator

Study Contact Takeda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/12/2022

Actual: 01/04/2025

Study start date

Planned: 30/09/2026

Date of final study report

Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda

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

Other

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

Assessing awareness and understanding of education materials for using VPRIV®

Data collection methods:

Primary data collection

Main study objective:

The main objective of this study is to assess the proportion of participants, caregivers and home infusion nurses who are aware of the Educational Material (EM) (home infusion guide, infusion diary, and safety and emergency plan), who understand the EM and use the EM.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

VPRIV

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

VELAGLUCERASE ALFA

Anatomical Therapeutic Chemical (ATC) code

(A16AB10) velaglucerase alfa

velaglucerase alfa

Medical condition to be studied

Gaucher's disease

Population studied

Short description of the study population

Patients, Caregivers and Home Infusion Nurses Based in the European Union

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

60

Study design details

Outcomes

1. Percentage of Participants/Caregivers who are Aware of EM 2. Percentage of Participants/Caregivers who Understand EM 3. Percentage of

Participants/Caregivers who Utilize EM 4. Percentage of Home Infusion Nurses Aware of EM 5. Percentage of Home Infusion Nurses who Understand EM 6. Percentage of Home Infusion Nurses who Utilize EM

Data analysis plan

Percentage of correct and appropriate answers about awareness and understanding of conditions of use of VPRIV® home infusion given by patients, caregivers and home infusion nurses will be assessed. Continuous variables will be described by the number of valid cases and missing data, mean, standard deviation (SD), median, Q1, Q3, minimum, and maximum. No missing data will be replaced. Categorical variables will be described as the total number and relative percentage per category. CIs of 95% will be calculated when relevant.

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)

Other

Patient surveys

Data sources (types), other

This is a survey among participants receiving VPRIV® home infusion, their caregivers and home infusion nurses who administer VPRIV® home infusion through non-nominative web-based questionnaires.

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