Survey among healthcare professionals (neurologists treating patients with MS along with MS specialist nurses) and patients in selected European countries plus Canada to evaluate the knowledge required for the safe use of Mayzent (siponimod)

First published: 22/12/2021

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS44782

Study ID

44783

DARWIN EU® study

No

Study countries

Canada

Croatia

Denmark

Germany

Netherlands

Spain

Sweden

Study description

The objective of this survey was to evaluate whether HCPs and patients/caregivers received the educational materials and to capture their knowledge of specific Mayzent (siponimod) safety measures.

The web-based survey was conducted in Germany, Netherlands, Spain, Croatia, Sweden, Denmark and Canada where Mayzent (siponimod) was available on the market and reimbursed for at least 6 months, to capture the knowledge and understanding of specific Mayzent safety measures by HCPs and patients/caregivers with access to Mayzent (siponimod).

A total sample of N=220 completed surveys from HCPs (161 neurologists treating patients with MS and 59 MS specialist nurses) and N=118 completed surveys from patients/caregivers were evaluated.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Novartis Clinical Disclosure Officer

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/05/2020

Actual: 27/05/2020

Study start date

Planned: 31/10/2021

Actual: 02/12/2021

Data analysis start date
Planned: 30/05/2025

Actual: 16/05/2025

Date of final study report
Planned: 31/10/2025

Actual: 24/10/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharmaceutical SA

Study protocol

CBAF312A2006-Amended protocol v1.4_Clean version_29Mar2021_Redacted.pdf (569.96 KB)

CBAF312A2006_ProtocolAmendment_V3_25Jan2024_Clean Version_Redacted.pdf (400.87 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)

Other study registration identification numbers and links

CBAF312A2006

Link to Clinicaltrials.gov

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Other

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

Evaluation education materials

Data collection methods:

Primary data collection

Study design:

The study included two distinct questionnaires

Main study objective:

The objective of this survey was to evaluate whether HCPs and patients/caregivers received the educational materials and to capture their knowledge of specific Mayzent (siponimod) safety measures.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multinational, questionnaire-based, cross-sectional survey to be conducted among 1) healthcare professionals and 2) patients/caregivers

Study drug and medical condition

Medicinal product name

MAYZENT

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

SIPONIMOD

Anatomical Therapeutic Chemical (ATC) code

(L04AE03) siponimod

siponimod

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

The study was conducted across two populations:

1. HCPs who prescribe, monitor and oversee the management / or provide in person medical

supervision of patients on Mayzent (siponimod). These included treating physicians as well as

MS specialist nurses

2. Patients/Caregivers of patients who are taking Mayzent (siponimod) to treat their MS and

according to the prescription of their neurologists

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

335

Study design details

Setting

The survey was administered in six European markets that represent distribution and prevalence of MS
and where Mayzent (siponimod) was available and reimbursed for at least six months (Germany,
Netherlands, Spain, Croatia, Sweden and Denmark), and Canada.

Data analysis plan

The analysis was descriptive in nature. For continuous variables, counts, means (with standard deviations), medians and ranges were provided. For categorical variables, frequencies and percentages (with 95% confidence intervals) were provided. Missing data was noted for each variable.

Documents

Study report

baf312a2006-CSR (2).pdf (1.31 MB)

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

For Healthcare professionals: eligibility materials administered through recruitment screener document, self-administered online survey questionnaire; For Patients: eligibility materials administered through recruitment screener document, self-administered online survey questionnaire

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