

A 24-week rPMS Study in Real-world Setting for Enerzair

Last Update: Jan 14, 2025

A 24-week Prospective, Open-label, Multicenter, Single-arm, Observational Regulatory Post-Marketing Surveillance (rPMS) Study in Real-world Setting (Mandatory by Local HA Regulation) for Enerzair (QVM149 150/50/80 µg o.d. and QVM149 150/50/160 µg o.d. Via Breezhaler)

ClinicalTrials.gov Identifier:

[NCT05274425](#)

Novartis Reference Number: CQVM149BKR01

[See if you Pre-qualify](#)

All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This surveillance was designed as a prospective, open-label, multicenter, single-arm, non-interventional, observational study to evaluate the safety and effectiveness of Enerzair inhalation capsule for up to 24 weeks under routine clinical practice. The two different doses of Enerzair inhalation capsule via Breezhaler will be prescribed according to the approved label information in Korea, and the investigation for any additional diagnostic or monitoring will be not conducted for this study.

Condition

Asthma

Overall Status

Recruiting

Number of Participants

600

Start Date

May 09, 2022

Completion Date

Mar 11, 2027

Gender

All

Age(s)

18 Years - 100 Years (Adult, Older Adult)

Interventions

Other

Enerzair 150/50/160 µg

There is no treatment allocation. Patients administered Enerzair by prescription that have started before inclusion of the patient into the study will be enrolled.

Other

Enerzair 150/50/80 µg

There is no treatment allocation. Patients administered Enerzair by prescription that have started before inclusion of the patient into the study will be enrolled.

Eligibility Criteria

Inclusion Criteria:

1. Adult patients (≥18 years of age) with a physician's diagnosis of asthma, who are prescribed Enerzair inhalation capsule (indacaterol acetate/ glycopyrronium bromide/mometasone furoate; 150/50/80, 150/50/160 µg) via Breezhaler, as per the approved label information
2. Patients who participate in the study after signing the consent form for data collection and use (Data Privacy ICF) after receiving a clear explanation of the objectives and nature of the study from the investigator

Exclusion Criteria:

1. Patients who are contraindicated for this medicinal product as described in the Precautions for Use in the label information (package insert) A. Patients with hypersensitivity reaction to this medicinal product or any of its constituents B. Because this medicinal product contains lactose, patients with hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption, etc.
2. Patients with acute asthma symptoms, including acute episodes of bronchospasm, for which a short-acting bronchodilator is required
3. Patients participating in other interventional clinical trials

Korea, Republic of

Novartis Investigative Site

Recruiting

Seoul,04763,Korea, Republic of

Novartis Investigative Site

Recruiting

Suncheon,Jeollanam Do,540-719,Korea, Republic of

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Worldwide Contacts

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Source URL: <https://uat2.arctic.novartis.com/clinicaltrials/study/nct05274425>

List of links present in page

1. <https://clinicaltrials.gov/ct2/show/NCT05274425>
2. [#trial-eligibility](#)
3. <tel:+41613241111>
4. <mailto:novartis.email@novartis.com>