

# Real world evidence data regarding galcanezumab efficacy in migraine prevention

## Emerald Medical Center, Romania

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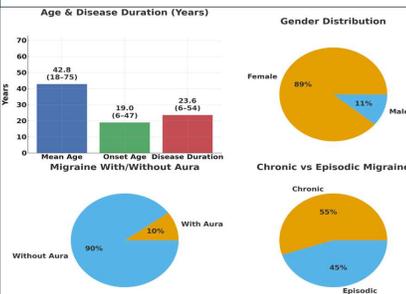
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### Introduction

Although migraine is among the most prevalent disabling disorders and most headache societies consider CGRP-targeted therapies as first line treatments, their accessibility and reimbursement criteria vary significantly between countries. At the time of writing this poster, Romania has only one reimbursed anti CGRP monoclonal antibody, galcanezumab. The prescription criteria are, fortunately, among the most patient-oriented in the world. The treatment is reimbursed if the patient experiences at least four migraine days per month, without the requirement of previous treatment failures.

### Methods and Materials

We conducted a retrospective analysis of the database from the Emerald Medical Centers in Bucharest and Iasi, focusing on demographic data, effectiveness and reported adverse effects during treatment with galcanezumab between January 2023 and September 2024. During this period, a total of 282 patients received treatment, 246 of whom were evaluated for at least 3 months, 207 for at least 6 months, 99 for at least 12 months and 67 for at least 18 months. Forty-two percent of the patients suffered from medication overuse headache. The average number of previously failed treatments was 1.6 although 32% of the patients had not received any prior preventive treatment.



### Discussion and conclusions

Despite the limitations of this being a retrospective report from a single network of medical centers, based primarily on anamnestic data from the database, the results are highly promising and support the early initiation of migraine treatment. Outcomes were particularly striking in patients for whom galcanezumab was the first prescribed preventive therapy.

Therapies targeting the CGRP pathway have a very good efficacy and safety profile, but with relatively high cost. Considering reports of sustained long-term efficacy even after short treatment courses (two cases also in our database), we believe that studies evaluating their efficacy under intermittent administration schedules could be valuable. We might consider even a single administration in the context of medication-overuse headache – in our cohort, the response rate for MOH patients was 72% starting from the first month, as they may help patients more easily overcome withdrawal from acute medication overuse.

### Results

The number of migraine days decreases from 16.66 to 5.92 in the first month of treatment, reaching 4.02 after 18 months. The overall response rate in the total patient cohort was 81% from the first month and remained relatively stable during the first 6 months, increasing to 91% - 88% at 12 and 18 months. A particularly noteworthy subgroup consisted of patients without any prior failed treatments. Their response rate was 87% from the first month, rising to 97% at one year.

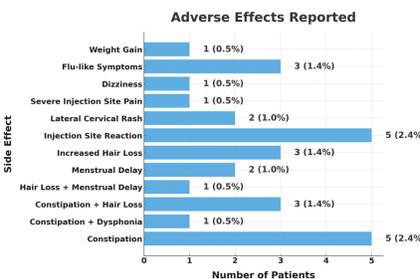
Seven patients (3.3%) discontinued treatment after periods ranging from 2 to 13 months due to lack of efficacy. Five patients had a history of anaphylactic shock (one patient experienced as many as five episodes); none developed adverse effects to galcanezumab. Three patients (1.4%) became pregnant during treatment (one patient terminated the pregnancy in the fourth month of gestation). The other patients delivered, and both the pregnancies and infants were without complications.

Two patients discontinued treatment after 3 months due to communication issues. Both patients had been responsive. In one case, migraine recurred 3 months after discontinuation, while the other patient (a woman in the perimenopausal period) remains in remission two years after treatment cessation.

Adverse events were reported in 28 patients (13.5%), with 4 patients (1.9%) discontinuing treatment due to these events. The most frequently reported adverse effects included:

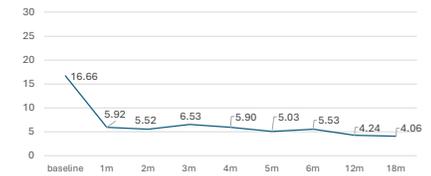
- Constipation: 5 patients (1 discontinued after 7 months), including 1 patient with concomitant dysphonia at first injection and 3 patients with concurrent increased hair loss.
- Increased hair loss: 4 patients (including 1 with delayed menstruation).
- Menstrual delay: 2 patients (1 discontinued after 9 months, partially due to a reduction of efficacy).
- Injection site reactions: 5 patients, including 1 severe pain (10/10).
- Lateral cervical rash: 2 patients.
- Dizziness: 1 patient (discontinued after 7 months).
- Flu-like symptoms: 3 patients (1 discontinued after 2 months).
- Weight gain: 1 patient

Percentages are expressed relative to the number of patients for whom data were available, not relative to the total number of patient.

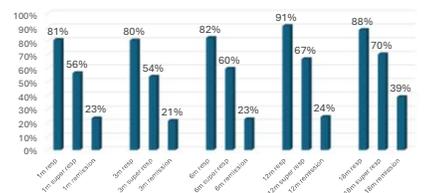


### Tables

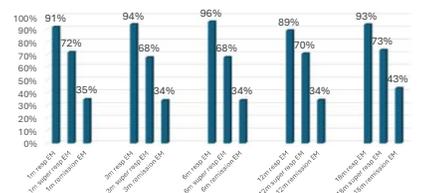
Monthly migraine days reduction



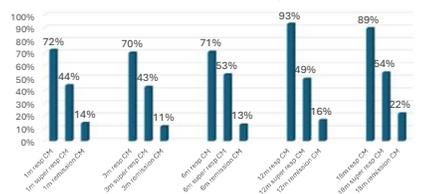
Responsiveness at 1, 3, 6, 12 and 18 months



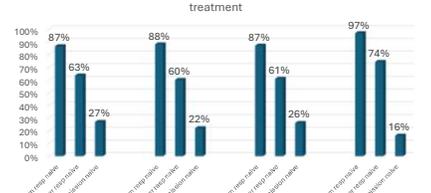
Responsiveness in episodic migraine



Responsiveness in chronic migraine



Responsiveness in patients without previous preventive treatment



Responsiveness in patients with medicine overuse headache

