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ATOGEPANT IN MIGRAINE PREVENTION: A NARRATIVE REVIEW OF PHARMACOLOGY, CLINICAL EFFICACY AND TOLERABILITY

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ABSTRACT

Migraine is a neurological disorder that involves trigeminal and vascular mechanisms. Pain associated with it is not the only issue. Migraine comes with a significant socioeconomic burden – reduced daily functioning, work productivity and general quality of life.

Treatment options for migraine include acute and preventive treatment. Conventional preventive treatments are not always the best option, considering adverse effects, contraindications, quite late benefits and poor long-term adherence.

The pathophysiology of migraine led us to the current main therapeutic target – calcitonin gene-related peptide (CGRP). Gepants, including atogepant, are CGRP signaling antagonists.

This narrative review analyzes atogepant's pharmacological profile, currently available evidence about clinical efficacy, tolerability and place of atogepant in migraine management.

KEYWORDS

Atogepant, Migraine Prevention, Gepants, Calcitonin Gene-Related Peptide, Chronic Migraine

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1. Introduction

Migraine is a condition characterized by recurrent headache attacks accompanied by other symptoms like nausea, photophobia, phonophobia and general functional impairment. Migraine affects a significant number of people worldwide and is one of the leading causes of years lived with disability.(Pescador Ruschel & De Jesus, 2026)

Migraine is classified by attack frequency as episodic migraine (headache occurring fewer than 15 days per month) or chronic migraine (headache occurring on at least 15 days per month) ('Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd Edition', 2018; Waliszewska-Prosół et al., 2025).

Migraine attacks affect individuals suffering from it not only through pain but also through reduced productivity, impaired social activity or sleep quality.

Acute treatments for patients suffering from severe attacks may be inadequate especially considering that regular use of acute treatment may lead to medication-overuse headache (MOH). Therefore, preventive treatment plays a crucial role in migraine management (Buse et al., 2019; Waliszewska-Prosół et al., 2025).

The decision to introduce preventive therapy should depend not only on the frequency of headache episodes but also on attack severity, response to acute medication, risk of medication overuse.

Traditional preventive treatments include beta-blockers, antiepileptic drugs, antidepressants and onabotulinumtoxinA. These options might be successful yet their use comes with adverse effects, contraindications, delayed onset of benefit, and poor long-term adherence. These flaws have contributed to the development of migraine-specific drugs that target CGRP, which is a neuropeptide correlated with migraine pathophysiology (Pellesi et al., 2024).

Atogepant is a CGRP antagonist developed for migraine prevention and offers a relatively short duration of action and flexible daily dosing (Ailani et al., 2021; R. Boinpally et al., 2024).

2. Methodology

A literature search was performed using PubMed and Google Scholar. Search terms included “atogepant”, “gepants”, “CGRP”, “episodic migraine”, “chronic migraine”, “migraine prevention”, and “migraine treatment”. Priority was given to randomized controlled trials, meta-analyses, clinical guidelines, regulatory documents, and relevant pharmacological studies published in English. Publications were included if they addressed the pharmacology, clinical efficacy, tolerability, safety, or clinical use of atogepant in migraine prevention. Publications were excluded if they were not available in English, did not concern migraine or CGRP-targeted treatment, or provided only limited information relevant to the aim of this review. Additional references were identified by screening the reference lists of selected publications.

This review was designed as a narrative review. The selected publications were analysed with attention to study population, intervention, comparator, treatment, efficacy outcomes, tolerability outcomes, and safety information. Particular attention was given to phase 3 clinical trials, considering these studies provide main evidence for current clinical use.

Data from pharmacological studies were also used to describe mechanism of action, pharmacokinetic features, and interaction profile.

The available evidence was summarized in a clinically oriented way, focusing on the role of atogepant in migraine prevention.

3. Pathophysiology of migraine

Migraine is described as a complex neurovascular disorder with possible genetic background (Pescador Ruschel & De Jesus, 2026). One of the main migraine pathophysiological mechanisms is activation of the trigeminovascular system.

Sensory fibers originating from the trigeminal ganglion that innervate the dura mater and cranial blood vessels activate, and that contributes to the transmission of nociceptive signals through the trigeminal nucleus caudalis and the trigeminocervical complex to higher brain regions involved in pain processing – brainstem, thalamus, hypothalamus, cerebral cortex (Puledda et al., 2023).

One of the most important neuropeptides involved in this pathway is CGRP, which is expressed in structures associated with migraine (trigeminal ganglion, trigeminocervical complex and sphenopalatine ganglion). When trigeminal afferent neurons activate, CGRP is released from perivascular nerve fibers and that contributes to vasodilation, neurogenic inflammation, peripheral sensitization and modulation of central nociceptive transmission.

Increased CGRP levels have been documented during spontaneous and triggered migraine attacks, and reduction of the neuropeptide concentration after the end of an attack. There have been observed elevated saliva and blood CGRP concentration during attacks, and also interictal serum CGRP concentrations have been demonstrated to be elevated in both episodic and chronic migraine. Furthermore, administration of CGRP can provoke migraine-like headache in susceptible individuals (Karsan et al., 2023; Puledda et al., 2023).

4. Current treatment options for migraine

4.1. Acute treatment

The goal of acute treatment is to relieve pain and associated symptoms, such as photophobia, phonophobia, osmophobia, nausea, and vomiting during an attack.

Commonly used medications include simple analgesics (acetaminophen, acetylsalicylic acid, ketoprofen, ibuprofen, metamizole), opioids (although generally not recommended because of the risk of dependence and association with MOH), triptans (sumatriptan, eletriptan, zolmitriptan), antiemetics, and newer drug classes such as gepants and ditans(Lew & Punnapuzha, 2026; Pellesi et al., 2024).

The choice of acute medication depends on attack severity, associated symptoms, previous response to used drugs, contraindications and patient preference. For some patients, simple analgesics might be sufficient, especially in mild headache episodes. Other patients might need migraine-specific acute treatment because of severity, rapid progression, or nausea and vomiting that restrict oral drug intake(Lew & Punnapuzha, 2026).

However, regular use of acute medications may cause MOH and does not address the need for reduction in attack frequency. Therefore, preventive therapy is advised for individuals with frequent, severe or poorly controlled migraine episodes (Pellesi et al., 2024; Waliszewska-Prosół et al., 2025).

4.2. Conventional preventive therapies

Preventive treatment options are offered to patients with impaired quality of life caused by regular migraine attacks. The goal of preventive treatment is to reduce attack frequency, severity, and migraine-related disability.

A measure of therapeutic success is at least a 50% reduction in monthly migraine days (MMDs) or attack frequency, without unacceptable adverse effects. However, treatment response should also be assessed in relation to functional improvement, reduced use of acute medication, and better patient tolerance of therapy.

Preventive treatment includes medication groups such as antihypertensives (propranolol, metoprolol, candesartan), antiepileptic drugs (topiramate, valproate), tricyclic antidepressants, selected selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, calcium channel blockers, and onabotulinumtoxinA. These therapeutic options remain important because of their accessibility, lower cost, and they are familiar to clinicians (Lampl et al., 2023; Pellesi et al., 2024; Waliszewska-Prosół et al., 2025).

4.3. CGRP-targeted therapies

Modern treatment options include medications targeting the CGRP signaling pathway, such as monoclonal antibodies and gepants.(Lipton et al., 2026)

There are four monoclonal antibodies available. They target the CGRP molecule (eptinezumab, fremanezumab, galcanezumab) or its receptor (erenumab). All of them have proven efficacious in both episodic and chronic migraine. Individuals who had previously experienced treatment failure with other drug classes also responded adequately(Aditya & Rattan, 2023).

In addition to monoclonal antibodies, CGRP-targeted therapies also include orally administered gepants (exception: zavegepant is administered intranasally). Ubrogepant and zavegepant are used for the acute treatment of migraine. Rimegepant has been approved for both acute and preventive treatment. Atogepant was developed specifically as an oral preventive therapy (Anukoolwittaya et al., 2025; Jakubowska & Sowa-Kućma, 2025; Martinelli et al., 2026; Pellesi et al., 2024; Waliszewska-Prosół et al., 2025).

5. Gepants as a new therapeutic class

The development of gepants has brought a major shift in migraine treatment – from non-specific preventive medications to migraine-specific therapy. Gepants share CGRP signaling antagonism, yet they differ in approved indications, routes of administration, dosing schedules, and available clinical evidence (Anukoolwittaya et al., 2025; Jakubowska & Sowa-Kućma, 2025).

5.1. Development of gepants

The major role of CGRP in migraine pathophysiology provided the rationale for the development of CGRP-targeted therapies – monoclonal antibodies and gepants. In contrast to monoclonal antibodies, gepants have a shorter duration of action and are mostly administered orally, whereas zavegepant is administered intranasally. All these features offer more flexible management in both acute and preventive therapy.(Lipton et al., 2026)

The first developed gepants proved clinically effective, however their development was discontinued because of safety concerns, especially hepatotoxicity. Given these limitations, the development of next-generation gepants with improved safety profiles was necessary. Atogepant belongs to this class and was developed specifically for the preventive treatment of migraine (Jakubowska & Sowa-Kućma, 2025; Karsan et al., 2023; Martinelli et al., 2026).

5.2. Available gepants

Currently used gepants share a common mechanism of action, but they have different routes of administration and clinical indications. Ubrogepant and zavegepant are indicated for the acute treatment of migraine. Rimegepant may be used for both acute and preventive treatment. Atogepant is used specifically for migraine prevention and is administered once daily (Jakubowska & Sowa-Kućma, 2025).

6. Pharmacological profile of atogepant

6.1. Pharmacodynamics

The pharmacodynamic activity of atogepant has been studied using a capsaicin-induced dermal vasodilation model – it served as an in vivo marker of CGRP-mediated vasodilation. In this model, atogepant inhibited CGRP-related vasodilation in both preclinical and human assessments, supporting its mechanism as a functional CGRP receptor blocker (R. Boinpally et al., 2024).

Pharmacodynamic data indicate that therapeutic oral doses of atogepant achieve plasma concentrations sufficient to inhibit CGRP receptor activity. After a total daily dose of 60 mg, concentrations associated with near-maximal inhibition were reached rapidly and maintained over a 24-hour period (R. Boinpally et al., 2024). Atogepant shows minimal penetration into the central nervous system, however it is possible that drug concentration in the cerebrospinal fluid is adequate for central action in migraine treatment due to atogepant's high affinity for CGRP receptors (R. R. Boinpally & Trugman, 2026). These findings support once-daily dosing of 60 mg atogepant (R. Boinpally et al., 2024).

6.2. Pharmacokinetics

After oral administration, atogepant is quickly absorbed and achieves pharmacologically relevant plasma concentrations within approximately 30 minutes, with a median time to maximum plasma concentration of about 2 hours. The terminal elimination half-life is approximately 11 hours. Pharmacokinetic parameters are dose-proportional and clinically relevant accumulation has not been observed with repeated dosing. These data support once-daily dosing in preventive therapy (R. Boinpally et al., 2024).

Food does not appear to have a clinically meaningful effect on atogepant exposure, and the medication has been administered without specific food restrictions in clinical studies (R. Boinpally et al., 2024).

Atogepant is primarily eliminated through hepatic metabolism, mainly via cytochrome P450 3A4 (CYP3A4). Considering this metabolic pathway, exposure to atogepant may be altered by strong CYP3A4 inhibitors or inducers. The drug is also a substrate of selected drug transporters, including organic anion transporting polypeptides (OATPs), which should be considered when evaluating potential drug-drug interactions (R. Boinpally et al., 2024; European Medicines Agency, 2024).

The main route of atogepant elimination is fecal excretion. Approximately 89% of total radioactivity was recovered, with about 81% recovered in the feces over 336 h (14 days) and about 8% recovered in the urine (R. R. Boinpally et al., 2025).

6.3. Safety and drug interactions

The safety of atogepant is closely related to its pharmacokinetic features and possible drug-drug interactions. This medication is primarily metabolized by CYP3A4 and simultaneous use of strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, ritonavir) may increase atogepant exposure. CYP3A4 inducers may reduce exposure and potentially decrease clinical efficacy. Therefore, simultaneous treatments should be reviewed before therapy initiation, particularly when drugs that strongly affect CYP3A4 are being used (European Medicines Agency, 2024).

Selected drug transporters, including organic anion-transporting polypeptides (OATPs) also play a significant role because atogepant is one of their substrates. Inhibitors of these transporters (e.g. rifampicin, ciclosporin, ritonavir) may increase systemic exposure to atogepant and dose adjustment or additional caution might be necessary. These interactions are particularly relevant, considering individuals suffering from migraine may use multiple acute and preventive drugs at once as well as medications for comorbid conditions (European Medicines Agency, 2024; Pellesi et al., 2024).

Atogepant appears to be generally safe and does not have relevant drug-drug interactions with several commonly used medications such as ethinyl estradiol/levonorgestrel, acetaminophen, naproxen, sumatriptan, ubrogepant, famotidine, esomeprazole. These findings support flexible management in clinical practice, although medication review remains relevant because atogepant exposure may still be affected by strong CYP3A4 modulators or transporter substrates (European Medicines Agency, 2024).

Mild to moderate renal or hepatic impairment generally does not require dose adjustment. However, severe renal impairment, end-stage renal disease, and severe hepatic impairment require caution. These data support atogepant's manageable interaction profile, but renal and hepatic function, and concomitant medication still need to be assessed before therapy initiation (R. Boinpally et al., 2024; European Medicines Agency, 2024).

7. Clinical efficacy of atogepant

The efficacy of atogepant in migraine treatment has been evaluated in randomized controlled trials and summarized in meta-analyses.

The primary outcome in most studies was the reduction in MMDs, compared with placebo. Additional benefits were also observed in secondary efficacy outcomes, including MHDs, acute medication use days, and the proportion of patients achieving at least a 50% reduction in MMDs (Hou et al., 2024; Shaukat et al., 2025).

7.1. Episodic migraine

The clinical efficacy of atogepant in episodic migraine has been evaluated in the ADVANCE trial. The study was a randomized, double-blind, placebo-controlled phase 3 trial.

Participants were assigned to receive atogepant at doses of 10 mg, 30 mg, 60 mg, or placebo once daily over a 12-week treatment period.

Atogepant proved significantly efficacious compared with placebo. The mean change from baseline in MMDs across the trial was -3.7 days (10 mg), -3.9 days (30 mg), -4.2 days (60 mg), and -2.5 days (placebo). In addition, a greater proportion of participants receiving medication achieved at least a 50% reduction in MMDs compared with placebo. These data support the efficacy of atogepant as an oral preventive drug for episodic migraine (Ailani et al., 2021).

The ELEVATE trial further supports the role of atogepant in patients with episodic migraine who had previously responded inadequately to conventional oral preventive therapies (Tassorelli et al., 2024).

7.2. Chronic migraine

The clinical efficacy in chronic migraine was studied in the phase 3 trial – PROGRESS. The trial was a randomized, double-blind, placebo-controlled study. Individuals with chronic migraine were randomized to receive atogepant 30 mg twice daily, atogepant 60 mg once daily or placebo for 12 weeks. Chronic migraine was defined as at least 15 MHDs with at least 8 MMDs. The study demonstrated clinically relevant reductions in MMDs in both atogepant dosing regimens compared with placebo.

A further analysis of the PROGRESS trial evaluated patients with and without acute medication overuse. In participants with acute medication overuse at least a 50% reduction in MMDs was achieved by a higher proportion of patients treated with atogepant 30 mg twice daily or 60 mg once daily compared with placebo. Similar benefits were also achieved by participants without acute medication overuse. These findings suggest that atogepant may be effective in chronic migraine regardless of baseline acute medication overuse status. PROGRESS participants treated with atogepant also had greater reductions in MHDs and acute medication use days compared with placebo. The mean difference, in individuals with acute medication overuse, was -2.8 days (30 mg twice daily) and -2.1 days (60 mg once daily). Both participants with and without acute medication overuse achieved greater reduction in acute medication use days compared with placebo.

At the end of the 12-week clinical trial, a smaller proportion of atogepant-treated participants continued to meet criteria for medication overuse (Goadsby et al., 2024).

The key clinical trials evaluating atogepant in migraine prevention are summarized in Table 1.

Table 1

Trial	Population	Study design	Intervention	Main efficacy findings
ADVANCE(Ailani et al., 2021)	Adults with episodic migraine	Phase 3, multicenter, randomized, double-blind, placebo-controlled trial	Atogepant 10 mg, 30 mg, or 60 mg once daily vs placebo for 12 weeks	Atogepant significantly reduced MMDs compared with placebo.
PROGRESS(Goadsby et al., 2024)	Adults with chronic migraine	Phase 3, randomized, double-blind, placebo-controlled trial	Atogepant 30 mg twice daily or 60 mg once daily vs placebo for 12 weeks	Atogepant reduced MMDs compared with placebo in patients with chronic migraine and in patients with acute medication overuse.
ELEVATE(Tassorelli et al., 2024)	Adults with episodic migraine and previous failure of conventional oral preventive treatments	Phase 3b, randomized, placebo-controlled trial	Atogepant 60 mg once daily vs placebo for 12 weeks	Atogepant demonstrated efficacy in a difficult-to-treat population with previous failure of two to four classes of conventional preventive therapies.

Abbreviations: BID, twice daily; MMDs, monthly migraine days; QD, once daily.

8. Tolerability

Tolerability is especially important aspect beceause preventive medication is taken regularly and for a prolonged period. Even mild adverse effects may influence adherence if they are persistent and affect daily comfort.

Overall, atogepant appears to be well tolerated in clinical trials. The most common treatment-emergent adverse events (TEAEs) were gastrointestinal symptoms (especially nausea and constipation), fatigue and upper respiratory tract infections. These TEAEs were generally mild to moderate and rarely led to treatment discontinuation (R. Boinpally et al., 2024).

Available data indicate that gastrointestinal TEAEs may be related to CGRP receptor blockade in the gastrointestinal tract and may be dose-dependent. However, clinically relevant differences between atogepant and placebo were not consistently observed across all TEAEs. Long-term safety data remain limited, and further studies are needed to better evaluate the safety profile of atogepant during long-term preventive treatment (Hou et al., 2024).

9. Discussion

Atogepant has practical advantages that support its use in contemporary migraine treatment. It is an orally administered medication offering migraine-specific action with no need for subcutaneous or intravenous administration. These facts may be relevant for patients who prefer oral therapy, have difficulty accepting injectable medication or require a therapy that can be discontinued or modified more easily than long-acting monoclonal antibodies. Patient preference is important, because preventive treatment requires regular use, follow-up and realistic expectations about time needed to observe the improvement. During clinical trials medication use is monitored very closely. In everyday world settings adherence might be decreased (Lipton et al., 2026; Russo et al., 2025; Tassorelli et al., 2024).

Another advantage of atogepant is its migraine-specific mechanism of action, unlike several conventional preventive drugs that were originally introduced for cardiovascular, psychiatric or neurological indications. Its mechanism directly targets CGRP signaling – a pathway strongly connected to migraine pathophysiology. Atogepant may therefore provide an alternative option for patients who poorly tolerate or respond inadequately to conventional preventive therapies. Also, a medication developed specifically for migraine prevention may be easier to explain to patients and this might influence patient acceptance. Emerging clinical and real-world data suggest potential usefulness in populations with previous preventive treatment failures (Russo et al., 2025; Tassorelli et al., 2024).

Despite its advantages, atogepant has limitations that should be considered when interpreting the current evidence. Its use may be limited by cost, reimbursement criteria, availability, and possible drug-drug

interactions, particularly because of its CYP3A4 metabolism. In addition, long-term real-world data remain more limited than for older preventive therapies, and not all patients respond adequately to CGRP-targeted treatments (Pellesi et al., 2024; Waliszewska-Prosół et al., 2025).

Future research should further evaluate the place of atogepant in migraine prevention and focus on identifying patients who are most likely to benefit from atogepant Although clinical trials have demonstrated efficacy and tolerability, additional long-term studies are needed to assess persistence, adherence, safety, and effectiveness across broader patient populations, including individuals with multiple comorbidities and prior treatment failures. Comparative studies are also needed to clarify how atogepant compares with conventional oral preventives, onabotulinumtoxinA, and monoclonal antibodies targeting the CGRP pathway. Better predictors of response could help clinicians select therapy more precisely and decrease treatment delays{Citation}.

Another important area for future investigation is the treatment sequencing. It remains unclear which patients should preferentially receive atogepant, monoclonal antibodies or other preventive therapies, and which specific clinical features may influence treatment response. Further studies may help determine the role of atogepant after therapy failure with monoclonal antibodies, its use in patients with medication overuse and its potential impact on patient-reported outcomes including quality of life functional impairment and treatment satisfaction (Russo et al., 2025).

10. Conclusions

Atogepant adds an oral option to the group of preventive migraine therapies targeting CGRP signaling. Evidence from randomized trials supports its efficacy in both episodic and chronic migraine, with reductions in MMDs, MHDs, acute medication use days, and improved responder rates. The tolerability profile observed in clinical studies appears acceptable, with gastrointestinal symptoms such as nausea and constipation among the most frequently reported TEAEs. In clinical practice, atogepant may be useful for patients who prefer non-injectable preventive treatment, have contraindications to conventional oral preventives or have not achieved adequate benefit with previous therapies.

Several questions remain unresolved. Long-term persistence, adherence, safety in broader real-world populations, and comparative effectiveness against monoclonal antibodies, onabotulinumtoxinA, and conventional oral preventives require further study. Overall, atogepant is a relevant oral preventive option for migraine, but its precise position in treatment algorithms should be defined by longer follow-up and comparative clinical data.

Conflicts of Interest: The author declares that there are no conflicts of interest.

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