



PRESS RELEASE

Canadian Migraine Sufferers Have New Treatment Option - Health Canada Approves UBRELVY® (ubrogepant tablet)

- *UBRELVY® is the first and only oral CGRP receptor antagonist (gepant) approved by Health Canada for the acute treatment of migraine*
- *UBRELVY® was demonstrated to reduce or eliminate migraine pain with a single oral tablet, with the flexibility to take an optional second dose for persistent pain*

Montreal, Quebec – November 16, 2022 – AbbVie (NYSE: ABBV) announced today that Health Canada has approved UBRELVY® (ubrogepant tablet) for the acute treatment of migraine, with or without aura, in adults.¹ UBRELVY® is the first orally-administered calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) for the treatment of migraine attacks once they start.

An estimated 2.7 million Canadians have been diagnosed with migraine, which is estimated to underrepresent today's migraine prevalence.² Migraine is a complex neurological disease with recurrent attacks that lasts 4-72 hours. It can be defined by symptoms such as moderate to severe pain intensity, nausea, vomiting, photophobia and phonophobia.³ It is one of the leading causes of disability in the world.⁴

"I see first-hand the incredible impact migraines can have on my patients. When you suffer an attack, some patients are forced to seek solitude and remove themselves from everything in their lives. It can be unbearable and impact one's interaction with family, friends, school and work," said Dr. Jonathan Gladstone, MD, FRCPC, neurologist and Director of the Gladstone Headache Clinic in Toronto. "Health Canada's approval of UBRELVY is an important step forward allowing physicians to provide a new migraine-specific option for migraine sufferers. The gepant class is one of the most evaluated targeted therapies for migraine treatment. I'm excited to have another treatment option available to help patients successfully manage their migraines."

Calcitonin gene-related peptide (CGRP) is a neuropeptide present in the peripheral and central nervous system. CGRP is released from sensory nerve endings during a migraine attack, particularly the nerve endings of sensory trigeminal ganglion neurons. Ubrogepant is a small molecule, high affinity ($K_i = 0.07\text{nM}$) CGRP receptor antagonist (gepant) that blocks the binding of CGRP to its receptor and antagonizes CGRP receptor function. UBRELVY® was demonstrated to reduce or eliminate migraine pain with a single oral tablet, with the flexibility to take an optional second dose for persistent pain.¹

"Migraine can often be a debilitating disease that can impact a person's ability to function and perform their daily routines. Being able to successfully address migraine attacks as they occur is essential," says Wendy Gerhart, Executive Director, Migraine Canada. "Migraine Canada welcomes the approval of UBRELVY® in Canada as a new and innovative treatment option. This will have a positive impact for the migraine community across the country."

The efficacy of UBRELVY® for the acute treatment of migraine was demonstrated in two multicenter, randomized, double-blind, placebo-controlled, single migraine attack studies. These studies enrolled patients with a history of migraine with and without aura, according to the ICHD-3 beta diagnostic criteria, and who experienced 2 to 8 migraine attacks per month with moderate to severe headache pain. In Study 1 (ACHIEVE I), patients were randomized to receive UBRELVY 50 mg or 100 mg or placebo; and in Study 2 (ACHIEVE II), patients were randomized to receive UBRELVY 50 mg or placebo. Patients were permitted to use standard migraine preventive medications during the study. At baseline, 23% percent of patients were taking preventive medications for migraine. The most commonly used preventive medications were topiramate, onabotulinumtoxinA, propranolol, and amitriptyline.¹

“UBRELVY® as the first oral gepant approved in Canada for the acute treatment of migraine is an important milestone in our commitment to bring innovative new medicines to Canadians with the goal make a meaningful difference for patients” says Tracey Ramsay, Vice President and General Manager, AbbVie Canada.

About UBRELVY® (ubrogepant tablet) ¹

UBRELVY® (ubrogepant tablet) is indicated for the acute treatment of migraine, with or without aura, in adults.

Calcitonin gene-related peptide (CGRP) is a neuropeptide present in the peripheral and central nervous system. CGRP is released from sensory nerve endings during a migraine attack, particularly the nerve endings of sensory trigeminal ganglion neurons. Ubrogepant is a small molecule, high affinity ($K_i = 0.07\text{nM}$) CGRP receptor antagonist (gepant) that blocks the binding of CGRP to its receptor and antagonizes CGRP receptor function. UBRELVY® was demonstrated to reduce or eliminate migraine pain with a single oral tablet, with the flexibility to take an optional second dose for persistent pain.

UBRELVY® is contraindicated:

- In patients with hypersensitivity to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container
- With concomitant use of strong CYP3A4 Inhibitors (e.g., ketoconazole, itraconazole, clarithromycin)

Please consult the UBRELVY® Product Monograph [here](#).

About AbbVie

AbbVie’s mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people’s lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women’s health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow AbbVie Canada on [Twitter](#), on [Instagram](#) or find us on LinkedIn.

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¹ UBRELVY Product Monograph. AbbVie Canada. November 2022.

² Ramage-Morin P., & Gilmour, H. (2014). Prevalence of migraine in the Canadian household population. Health Reports, 25(6): 10-16. <https://www150.statcan.gc.ca/n1/en/pub/82-003-x/2014006/article/14033-eng.pdf?st=CSyp19VF>. Accessed November 2022.

³ Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders, 3rd edition. *Cephalalgia*. 2018;38(1):1-211.

⁴ Steiner, T.J., Stovner, L.J., Jensen, R. et al. Migraine remains second among the world's causes of disability, and first among young women: findings from GBD2019. J Headache Pain 21, 137 (2020). <https://doi.org/10.1186/s10194-020-01208-0>