

Sumitomo Pharma and Pfizer Canada Announce Availability of MYFEMBREE® in Canada

MISSISSAUGA, ON and KIRKLAND, QC, Jan. 31, 2024 [/PRNewswire/](#) -- In partnership with Sumitomo Pharma Canada, Inc., Pfizer Canada ULC is proud to announce that supply of MYFEMBREE® (relugolix 40 mg, estradiol 1 mg and norethindrone acetate tablets 0.5 mg tablets) is now available in Canada by prescription for the management of moderate to severe pain associated with endometriosis in pre-menopausal women, as well as for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women.¹

"For many fibroid and endometriosis patients, symptoms can be debilitating. These conditions progress for years, while women are simultaneously managing jobs and families," said Patricia Lee, Founder of CANFib (Canadian Women with Fibroids). "MYFEMBREE being added to Canada's toolbox means women with endometriosis and uterine fibroids have much-needed access to new treatment options for their symptoms."



"The introduction of MYFEMBREE represents a significant advance in the care of pre-menopausal patients battling with endometriosis and uterine fibroids," said Dr. Jamie Kroft, Deputy Chief, Obstetrics & Gynaecology - Minimally Invasive Gynaecologic Surgery at Sunnybrook Health Sciences Centre and Associate Professor, at the University of Toronto. "Providing new options for managing these conditions is a positive step forward in supporting patients' well-being and offering renewed optimism in their treatment journey."

As previously announced, Pfizer Canada ULC will lead commercialization efforts of MYFEMBREE for both the uterine fibroid and endometriosis indications in Canada.

About Uterine Fibroids

Uterine fibroids are the most common benign tumors in women of reproductive age.² Uterine fibroids may be underdiagnosed due to several factors. Roughly 50 to 80% of women may have asymptomatic fibroids, meaning they don't experience noticeable symptoms. Additionally, some women with fibroid-related symptoms, such as heavy menstrual bleeding and pain, might not seek medical attention because they consider these issues to be a normal part of their menstrual cycles. Furthermore, healthcare providers may sometimes dismiss these symptoms as normal, contributing to the underestimation of uterine fibroid prevalence in Canadian women.^{3,4,5,6}

About Endometriosis

Endometriosis is a chronic disease characterized by growth of endometrial-like tissue outside the uterus.⁷ This growth of endometriotic tissue relies on estrogen, a hormone crucial for regulating the female reproductive system.⁸ Endometriosis mainly affects women of reproductive age, occurring between their first menstrual period and menopause, when estrogen levels decline.⁹ In Canada, 7.0% of women aged 18-48 have endometriosis, with an average diagnosis age of 27.9. Most Canadian women with endometriosis experience symptoms before diagnosis with an average delay of 5.4 years in diagnosis.¹⁰ Symptoms include menstrual pain, pelvic pain, and pain during sex, with 60% reporting moderate to severe pain.^{6,9,11} Endometriosis can impact fertility, quality of life, and work productivity.¹²

About MYFEMBREE®

MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg tablets) was recently approved by Health Canada making it the first oral prescription treatment approved for both the management of heavy menstrual bleeding associated with uterine fibroids and for the management of moderate to severe pain associated with endometriosis in pre-menopausal women. MYFEMBREE was approved by the U.S. Food and Drug Administration for the treatment of heavy menstrual bleeding associated with uterine fibroids in May 2021 and for the management of moderate to severe pain associated with endometriosis in August 2022.

About Sumitomo Pharma

Sumitomo Pharma Co., Ltd. is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.), Canada (Sumitomo Pharma Canada, Inc.) and Europe (Sumitomo Pharma Switzerland GmbH) focused on addressing patient needs in psychiatry & neurology, oncology, urology, women's health, rare disease, and cell & gene therapies. With several marketed products in the U.S., Canada, and Europe, a diverse pipeline of early- to late-stage assets, and in-house advanced technology capabilities, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information, please visit <https://www.us.sumitomo-pharma.com> or follow us on [LinkedIn](#).

About Pfizer Canada

Pfizer Canada ULC is the Canadian operation of Pfizer Inc., one of the world's leading biopharmaceutical companies. At Pfizer, we apply science and our global resources to bring therapies to people that help extend and improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products. Every day, Pfizer colleagues work to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. To learn more about Pfizer Canada, visit pfizer.ca or you can follow us on [LinkedIn](#), [Facebook](#), [X](#), [Instagram](#) or [YouTube](#).

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¹ Cision Newswire. [Sumitomo Pharma and Pfizer in Canada Receive Health Canada Approval for MYFEMBREE](#). October 19, 2023. Accessed on December 15, 2023

² BMC Public Health, Global, regional, and national time trends in incidence, prevalence, years lived with disability for uterine fibroids, 1990–2019: an age-period-cohort analysis for the global burden of disease 2019 study, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15765-x>, Accessed August 22, 2023

³ Laberge PY, Vilos GA, Vilos AG, Janiszewski PM. Burden of symptomatic uterine fibroids in Canadian women: a cohort study. *Curr Med Res Opin.* 2016;32(1):165-75. doi:10.1185/03007795.2015.1107534

⁴ Bukulmez O, Doody KJ. Clinical features of myomas. *Obstet Gynecol Clin North Am.* Mar 2006;33(1):69-84. doi:10.1016/j.ogc.2005.12.002

⁵ Stovall DW. Clinical symptomatology of uterine leiomyomas. *Clin Obstet Gynecol.* Jun 2001;44(2):364-71. doi:10.1097/00003081-200106000-00022

⁶ Zimmermann A, Bernuit D, Gerlinger C, Schaefers M, Geppert K. Prevalence, symptoms and management of uterine fibroids: an international internet-based survey of 21,746 women. *BMC Women's Health.* Mar 26 2012;12:6.

⁷ Zondervan, K.T., et al., Endometriosis. *Nat Rev Dis Primers*, 2018. 4(1): p. 9.

⁸ Ahn, S.H., et al., Pathophysiology and immune dysfunction in endometriosis. *BioMed research international*, 2015. 2015.

⁹ Stratton, P. and K.J. Berkley, Chronic pelvic pain and endometriosis: translational evidence of the relationship and implications. *Hum Reprod Update*, 2011. 17(3): p. 327-46.

¹⁰ Singh, S., et al., Prevalence, symptomatic burden, and diagnosis of endometriosis in Canada: cross-sectional survey of 30 000 women. *Journal of Obstetrics and Gynaecology Canada*, 2020. 42(7): p. 829-838.

¹¹ Becker, K., et al., Real world data on symptomatology and diagnostic approaches of 27,840 women living with endometriosis. *Scientific Reports*, 2021. 11(1): p. 1-9.

¹² Macer, M.L. and H.S. Taylor, Endometriosis and infertility: a review of the pathogenesis and treatment of endometriosis-associated infertility. *Obstetrics and Gynecology Clinics*, 2012. 39(4): p. 535-549.



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