

Sumitomo Pharma and Pfizer in Canada Receive Health Canada Approval for MYFEMBREE®

MISSISSAUGA, ON and KIRKLAND, QC, Oct. 19, 2023 [/PRNewswire/](#) -- Sumitomo Pharma Canada, Inc. and Pfizer Canada today announced that Health Canada has granted a Notice of Compliance (NOC) for MYFEMBREE (Relugolix, estradiol and norethindrone acetate tablets) for the management of moderate to severe pain associated with endometriosis in pre-menopausal women on October 17, 2023. On September 22, 2023, Health Canada also approved MYFEMBREE for the management of heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. This combination therapy oral treatment is taken once daily and provides a new option for women to manage their symptoms related to endometriosis and uterine fibroids.

"Health Canada's approval of MYFEMBREE across the uterine fibroid and endometriosis indications marks a significant milestone in our commitment to women's health," said Lisa Mullett, General Manager, Sumitomo Pharma Canada, Inc. "These are multi-faceted and complex chronic conditions, and we are proud to make new treatment options available to women in Canada."

"MYFEMBREE's approval is a testament to the shared commitment between our two companies to support women's health," added Andréa Mueller, Primary Care Portfolio Lead at Pfizer Canada. "We are proud to help women manage their health at all stages of their lives."

This approval is based on several comprehensive Phase 3 studies, including the LIBERTY 1 and LIBERTY 2 trials for uterine fibroids and the SPIRIT 1 and SPIRIT 2 trials for endometriosis.

"Uterine fibroids and endometriosis are very common conditions affecting millions of Canadians. Endometriosis, in particular, can be a very challenging and complex condition to treat, often resulting in years of delay to diagnosis, said Dr. Sony Sukhbir Singh, Professor and Chair of the Department of Obstetrics and Gynecology, at the University of Ottawa. "These conditions can cause debilitating symptoms such as pain and bleeding, impacting daily life and overall well-being for many girls, women and gender diverse individuals."

Following this approval Pfizer Canada will lead commercialization efforts of MYFEMBREE in the uterine fibroid and endometriosis indications. In partnership with Sumitomo Pharma in Canada, Pfizer Canada is currently assessing the timeline of availability for MYFEMBREE and are committed to bringing supply of this medicine to Canadians as quickly as possible.

About Uterine Fibroids

Uterine fibroids are the most common benign tumors in women of reproductive age.¹ 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.^{2,3,4,5}

About Endometriosis

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

About MYFEMBREE®

MYFEMBREE® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) has received a dual indication approval, making it the first Health Canada-approved oral treatment to manage uterine fibroids and endometriosis. 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. Our diversified healthcare portfolio includes some of the world's best known and most prescribed medicines and vaccines. We apply science and our global resources to improve the health and well-being of Canadians at every stage of life. Our commitment is reflected in everything we do, from our disease awareness initiatives to our community partnerships. To learn more about Pfizer Canada, visit pfizer.ca or you can follow us on [LinkedIn](#), [Facebook](#), [Twitter](#) or [YouTube](#).

¹ 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

² 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:10.1185/03007995.2015.1107534

³ Bukulmez O, Doody KJ. Clinical features of myomas. *Obstet Gynecol Clin North Am.* Mar 2006;33(1):69-84. doi:10.1016/j.jogc.2005.12.002

⁴ Stovall DW. Clinical symptomatology of uterine leiomyomas. *Clin Obstet Gynecol.* Jun 2001;44(2):364-71. doi:10.1097/00003081-200106000-00022

⁵ Zimmermann A, Bernuit D, Gerlinger C, Schaefer 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.

⁶ Zondervan, K.T., et al., Endometriosis. *Nat Rev Dis Primers*, 2018. 4(1): p. 9.

⁷ Ahn, S.H., et al., Pathophysiology and immune dysfunction in endometriosis. *BioMed research international*, 2015. 2015.

⁸ 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.

⁹ 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.

¹⁰ 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.

¹¹ 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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