Myfembree can help premenopausal women with disruptive heavy menstrual bleeding from uterine fibroids[1]

The recommended total duration of treatment is 24 months.

Myfembree®
(relugolix, estradiol, and norethindrone acetate) tablets
40 mg, 1 mg, 0.5 mg

Signs that she's not experiencing the relief she needs[2,3]:

- She bleeds for more than 7 days
- One pad/tampon at a time is not enough
- She feels dizzy and fatigued due to her UF-related HMB

Not an actual patient.
HMB = heavy menstrual bleeding; UF = uterine fibroids.

INDICATION

Myfembree is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitations of Use: Use of Myfembree should be limited to 24 months due to the risk of continued bone loss which may not be reversible.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: THROMBOEMBOLIC DISORDERS AND VASCULAR EVENTS

- **Estrogen and progestin combination products, including Myfembree, increase the risk of thrombotic or thromboembolic disorders including pulmonary embolism, deep vein thrombosis, stroke and myocardial infarction, especially in women at increased risk for these events.**
- **Myfembree is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and those at increased risk for these events, including women >35 years of age who smoke or with uncontrolled hypertension.**

CONTRAINDICATIONS

Myfembree is contraindicated in women with: high risk of arterial, venous thrombotic, or thromboembolic disorder; pregnancy; known osteoporosis; current or history of breast- or other hormone-sensitive cancers; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known hypersensitivity to components of Myfembree.

Please scroll for additional Important Safety Information and click for full Prescribing Information, including BOXED WARNING

MYFEMBREE DELIVERED POWERFUL REDUCTIONS IN BLEEDING AT WEEK 24[4]

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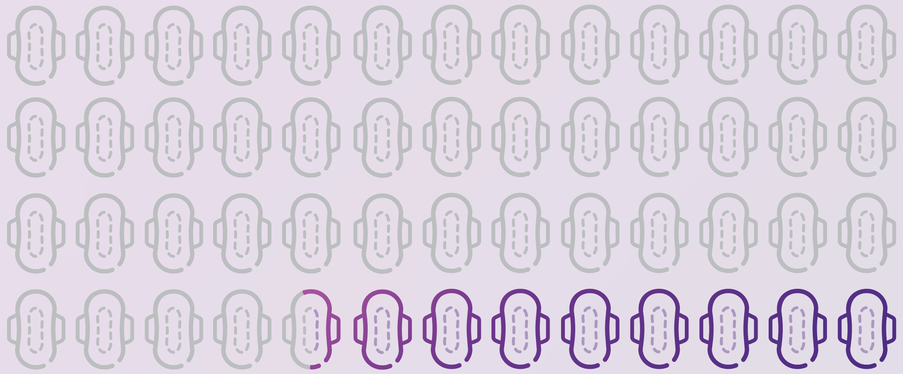
PRIMARY ENDPOINT

7 out of 10 WOMEN TAKING MYFEMBREE SAW THEIR BLEEDING LESSEN BY AT LEAST HALF ***AND*** TO <80 mL BY THE LAST 35 DAYS OF TREATMENT vs 2 OUT OF 10 FOR PLACEBO, (71.7% vs 15.7%).[4,*]

KEY SECONDARY ENDPOINT



Women on Myfembree had

84%

lighter periods[4,†,‡]

LS mean percent reduction in MBL volume at Week 24, 83.7% compared with placebo at 17.2%.[4,*]

Lighter periods were seen within 1 cycle[4]

LS mean percent reduction in MBL volume at Week 4, 50.8% compared to placebo at 12.7%.[4]
MBL volume assessment at Week 4 was a prespecified key secondary endpoint, but was not adjusted for multiplicity.[5]

Trial Design: Myfembree was studied in two 24-week, randomized, double-blind, placebo-controlled clinical trials (LIBERTY 1 and 2), evaluating 768 premenopausal women with heavy menstrual bleeding associated with uterine fibroids.[1]

IMPORTANT SAFETY INFORMATION *(Cont'd)*
WARNINGS AND PRECAUTIONS

Thromboembolic Disorders: Discontinue immediately if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs or is suspected; or if there is sudden unexplained partial or complete loss of vision, proptosis, diplopia, papilledema or retinal vascular lesions and evaluate for retinal vein thrombosis. Discontinue ≥4 to 6 weeks before surgery associated with an increased risk of thromboembolism or during prolonged immobilization.

Bone Loss: Myfembree may decrease bone mineral density (BMD) in some patients, which may be greater with longer use and may not be completely reversible. Consider the benefits and risks in patients with a history of low trauma fracture or risk factors for osteoporosis or bone loss. Assessment of BMD by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter.

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*Data shown represent results from a pooled post hoc analysis of LIBERTY 1 and 2; this endpoint at Week 24 was statistically significant in each study (LIBERTY 1: $P<0.0001$, LIBERTY 2: $P<0.0001$).[1,4]
†An LS mean baseline MBL volume was 258.4 mL, which equates to approximately 52 pads over the course of a menstrual cycle. 1 fully saturated day pad holds approximately 5 mL.[4,6]
‡Myfembree (n = 247); placebo (n = 242).[4]

LS = least squares; MBL = menstrual blood loss; *P* = *P* value.

MYFEMBREE IS *PURPOSEFULLY* DESIGNED TO RELIEVE BLEEDING FROM UTERINE FIBROIDS WHILE *MITIGATING* SIDE EFFECTS

like bone loss, associated with relugolix alone[1,5,7,8]

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Not actual pill size.[4]

Myfembree is the *only* once daily pill that combines[1,5,8]

GnRH antagonist		Purposeful low-dose add-back therapy (ABT)		
Relugolix (40 mg)	+	**E2** (1 mg)		**NETA** (0.5 mg)
Reduces hormones like estradiol, relieving bleeding from uterine fibroids		Could offset potential bone loss due to low estradiol from relugolix alone[5]		Protects the uterus from the effects of estrogen alone[1]

Adverse Reactions

Most common adverse reactions (incidence ≥3% and greater than placebo) were vasomotor symptoms, abnormal uterine bleeding, alopecia, and decreased libido.[1]

IMPORTANT SAFETY INFORMATION *(Cont'd)*

WARNINGS AND PRECAUTIONS *(Cont'd)*

Hormone-Sensitive Malignancies: Discontinue Myfembree if a hormone-sensitive malignancy is diagnosed. Breast exams and mammography are recommended. Use of estrogen alone or estrogen plus progestin has resulted in abnormal mammograms requiring further evaluation.

Suicidal Ideation and Mood Disorders (Including Depression): Evaluate patients with a history of suicidal ideation, depression, and mood disorders before starting treatment. Monitor for these symptoms including shortly after initiating treatment. Advise patients to seek medical care for new or worsening depression, anxiety, other mood changes, or suicidal ideation and behavior. Gonadotropin-releasing hormone receptor antagonists, including Myfembree, have been associated with mood disorders (including depression) and suicidal ideation.

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E2 = estradiol; GnRH = gonadotropin-releasing hormone; NETA = norethindrone acetate.

Help your patients get started on Myfembree

Learn More About Copay Coverage

IMPORTANT SAFETY INFORMATION *(Cont'd)*
WARNINGS AND PRECAUTIONS *(Cont'd)*

Hepatic Impairment and Transaminase Elevations: Due to poor metabolism of steroid hormones, instruct these patients to promptly seek medical care for symptoms/signs of liver injury, e.g., jaundice or right upper abdominal pain. Acute liver test abnormalities may require discontinuing Myfembree until tests return to normal and Myfembree causation is excluded.

Gallbladder Disease or History of Cholestatic Jaundice: Discontinue Myfembree if signs/symptoms of gallbladder disease or jaundice occur. Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease.

Elevated Blood Pressure: In women with well-controlled hypertension, monitor blood pressure and stop Myfembree if it rises significantly.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy: Advise women to use non-hormonal contraception during and for one week after discontinuing Myfembree. Avoid use with hormonal contraceptives. Myfembree may delay recognition of pregnancy because it alters menstrual bleeding. Test for pregnancy if suspected and discontinue Myfembree if confirmed.

Risk of Early Pregnancy Loss: Myfembree can cause early pregnancy loss. Exclude pregnancy before initiating and advise women to use non-hormonal contraception.

Uterine Fibroid Prolapse or Expulsion: Advise women with known or suspected submucosal uterine fibroids about the risk of uterine fibroid prolapse or expulsion and instruct them to contact their physician if severe bleeding/cramping occurs.

Alopecia: Alopecia, hair loss, and hair thinning were reported with Myfembree. Whether hair loss is reversible is unknown.

Effects on Carbohydrate and Lipid Metabolism: More frequent monitoring in women with prediabetes and diabetes may be necessary. Myfembree may decrease glucose tolerance and increase blood glucose concentrations. Monitor lipid levels and consider discontinuing if hypercholesterolemia or hypertriglyceridemia worsens. In women with pre-existing hypertriglyceridemia, estrogen therapy may increase triglycerides levels leading to pancreatitis. Myfembree is associated with increases in total cholesterol and LDL-C.

Effect on Other Laboratory Results: Patients with hypothyroidism and hypoadrenalism may require higher doses of thyroid hormone or cortisol replacement therapy. Combined estrogen and progestin may raise serum concentrations of binding proteins, which may reduce free thyroid or corticosteroid hormone levels. Estrogen and progestin may also affect the levels of sex hormone-binding globulin and coagulation factors.

Hypersensitivity Reactions: Immediately discontinue Myfembree if a hypersensitivity reaction occurs.

ADVERSE REACTIONS: Most common adverse reactions (incidence ≥3% and greater than placebo) were vasomotor symptoms, abnormal uterine bleeding, alopecia, and decreased libido. These are not all the possible side effects.

LACTATION: Advise women not to breastfeed while taking Myfembree.

Please see full Prescribing Information, including BOXED WARNING

References: 1. Myfembree [Prescribing Information]. Sumitomo Pharma America, Inc. July 2024. **2.** American College of Obstetricians and Gynecologists. Heavy and abnormal periods. Accessed March 13, 2025. https://www.acog.org/womens-health/faqs/heavy-and-abnormal-periods **3.** American College of Obstetricians and Gynecologists. Heavy menstrual bleeding. Accessed March 13, 2025. https://www.acog.org/womens-health/faqs/heavy-menstrual-bleeding **4.** Data on file. Sumitomo Pharma America, Inc. **5.** Al-Hendy A, Lukes AS, Poindexter AN III, et al. Treatment of uterine fibroid symptoms with relugolix combination therapy. *N Engl J Med*. 2021;384(7):630-642. **6.** Wyatt KM, Dimmock PW, Walker TJ, O'Brien PM. Determination of total menstrual blood loss. *Fertil Steril*. 2001;76(1):125-131. **7.** Arjona Ferreira JC, Migoya E. Development of relugolix combination therapy as a medical treatment option for women with uterine fibroids or endometriosis. *F S Rep*. 2022;4(2S):73-82. **8.** Friedman AJ, Lobel SM, Rein MS, Barbieri RL. Efficacy and safety considerations in women with uterine leiomyomas treated with gonadotropin-releasing hormone agonists: the estrogen threshold hypothesis. *Am J Obstet Gynecol*. 1990;163(4):1114-1119.

Sumitomo Pharma

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