

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

MYFEMBREE

Relugolix, estradiol and norethindrone acetate tablets

Read this carefully before you start taking **MYFEMBREE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MYFEMBREE**.

Serious Warnings and Precautions

Blood clot problems:

- Taking MYFEMBREE can increase your risk of developing blood clot disorders such as clots in your legs (deep vein thrombosis), lungs (pulmonary embolism), stroke and heart attack. This risk is especially higher in women at increased risk for developing blood clot disorders.
- Do not take MYFEMBREE if you:
 - have or had a history of blood clots disorders, or
 - are at an increased risk for developing blood clot disorders (e.g. obese, diabetes), or
 - are over 35 years of age who smokes, or
 - have uncontrolled high blood pressure.

What is MYFEMBREE used for?

MYFEMBREE is used in premenopausal adult women to manage:

- heavy menstrual bleeding related to uterine fibroids
- moderate to severe pain associated with endometriosis

How does MYFEMBREE work?

The three medicinal ingredients in MYFEMBREE work by:

- Relugolix: acts by lowering the amount of hormones called estrogen and progesterone. This lowers the bleeding associated with uterine fibroids and the pain associated with endometriosis.
- Estradiol (an estrogen): lowers the risk of bone loss.
- Norethindrone acetate (a progestin): lowers the risk of irregular thickening of the womb lining and is necessary when women with a uterus (womb) take estrogen.

What are the ingredients in MYFEMBREE?

Medicinal ingredients: relugolix, estradiol, and norethindrone acetate

Non-medicinal ingredients: hydroxypropyl cellulose, hypromellose, iron oxide yellow, lactose monohydrate, magnesium stearate, mannitol, sodium starch glycolate, titanium dioxide, triacetin.

MYFEMBREE comes in the following dosage form:

Tablet: relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg

Do not use MYFEMBREE if:

- you are allergic to relugolix, estradiol, norethindrone acetate or any of the other ingredients of this medicine or container.
- you have or have had blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism).
- you have or have had previously have had a disease caused by blood clots in the arteries. Examples are heart attack, stroke or angina.
- you have a blood clotting disorder. Examples such as protein C deficiency, protein S deficiency, antithrombin-III deficiency, or Factor V Leiden.
- You are 35 years of age or above and suffer from:
 - headaches with symptoms such as paralysis or loss of muscle control, or
 - migraines with visual disturbance
- you have uncontrolled high blood pressure.
- you smoke and are over 35 years of age.
- you have osteoporosis.
- you have, suspect you have or have a history of breast cancer.
- you have, suspect you have or had any type of hormone-sensitive cancer (e.g. endometrial cancer) or you have a higher risk developing a hormone-sensitive cancer.
- you have or ever had liver tumours.
- you have or ever had a liver disease and your liver function tests have not returned to normal.
- you are pregnant or think you might be pregnant. MYFEMBREE can cause early pregnancy loss.
- you are breastfeeding. Talk to your healthcare professional about the best way to feed your baby if you take MYFEMBREE.
- you are using hormonal birth control.
- you have any genital bleeding of unknown origin.
- you have partial or complete loss of vision from vascular eye disease.
- you have endometrial hyperplasia, which is when there is an irregular thickening of the uterine lining.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MYFEMBREE. Talk about any health conditions or problems you may have, including if you:

- have prediabetes or diabetes.
- have high triglycerides (fats) levels in blood.
- are scheduled for surgery or will be on bed rest. MYFEMBREE may increase your risk of blood clots after surgery. Your healthcare professional may advise you to stop taking MYFEMBREE 4 to 6 weeks before you have surgery. Talk to your healthcare professional about when to stop MYFEMBREE before surgery and when to restart MYFEMBREE after surgery.
- had gallbladder problems related to estrogen use or pregnancy.
- have or have had broken bones or other conditions that may cause bone problems. Including taking any medications that may weaken your bone.
- have or have had depression, mood swings, or suicidal thoughts or behavior.
- need a blood or urine test, because MYFEMBREE can affect the results of some tests, including thyroid, steroid, hormone, cholesterol, and blood clotting.

Other warnings you should know about:

Bone problems: Taking MYFEMBREE can cause bone loss. Your healthcare professional may conduct an x-ray to monitor your bone health. You are more at risk of experiencing bone loss if you:

- have a history of a low trauma fracture and are at risk of developing osteoporosis.
- take medication that may decrease your bone density (e.g. systemic or chronic inhaled corticosteroids, anticonvulsants, or chronic use of proton pump inhibitors).
- are taking MYFEMBREE for a longer period of time

High blood pressure: Taking MYFEMBREE may cause high blood pressure. See your healthcare professional to check your blood pressure regularly.

High blood sugar and fats:

- Treatment with MYFEMBREE can cause high blood sugar. Your healthcare professional will monitor your blood sugar levels.
- Taking MYFEMBREE can increase your blood cholesterol. Your healthcare professional will monitor the fat levels in your blood and may stop treatment if your levels are high. You may be at a great risk of developing pancreatitis if you already have high triglyceride (fat) levels in the blood.

Breast examination: Your healthcare professional may conduct a breast examination and mammography.

Pregnancy testing: MYFEMBREE can decrease your menstrual bleeding or result in no menstrual bleeding at all. This may make it hard to know if you are pregnant. Watch for other signs of pregnancy such as breast tenderness, weight gain and nausea.

Birth control: Take non-hormonal birth control during your treatment and for one week after you end your treatment. Using an estrogen hormonal birth control may affect how MYFEMBREE works.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MYFEMBREE:

- erythromycin
- rifampin

How to take MYFEMBREE

- Take exactly as your healthcare professional tells you to take it.
- Take at about the same time each day with or without food. Take the tablet with a little liquid, as needed.
- Avoid taking with oral P-gp inhibitors medications. If you have to take oral P-gp inhibitors, take MYFEMBREE first and wait at least 6 hours before taking the P-gp inhibitor. Ask your healthcare provider if you are not sure if you are taking this type of medicine.
- Your healthcare professional may:
 - give you a pregnancy test before you start taking MYFEMBREE.
 - Stop you from taking any hormonal birth control before you begin taking MYFEMBREE.
- You should begin MYFEMBREE as soon as possible after your period begins, within the first 5 days after the start of bleeding due to your period. If you start at another time of your menstrual cycle, your period may become heavy or irregular.

- If you would like to stop taking MYFEMBREE, talk to your healthcare professional first. Your healthcare professional will explain the effects of stopping treatment and discuss other possibilities with you.

Usual dose:

Take one tablet orally once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much MYFEMBREE contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take the missed dose as soon as you remember on that day, and then take MYFEMBREE at the usual time the next day. Do not take a double dose to make up for a forgotten tablet.

What are possible side effects from using MYFEMBREE?

These are not all the possible side effects you may have when taking MYFEMBREE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- back pain
- being irritable
- decreased interest in sex
- hair loss or hair thinning
- headache
- hot flushes
- increased sweating
- indigestion
- joint pain
- night sweats

MYFEMBREE can cause abnormal blood test results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
New or worsening depression, anxiety or other mood changes		√	
Thought of ending one’s life (suicidal ideation)			√
High blood pressure		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Pulmonary embolism (Blood clot in the lung): sharp pain in the chest, coughing blood, sudden shortness of breath			√
Deep vein thrombosis (Blood clot in the leg): pain in the calf, swelling, redness, skin feeling “warm to the touch”			√
Myocardial Infarction (Heart attack): crushing chest pain or heaviness, heartburn, shortness of breath, nausea, cold sweat, dizziness			√
Stroke: sudden severe or worsening headache, vomiting, dizziness, fainting, vision or speech problems, weakness or numbness in the arm or leg			√
Blood clot on the eye: sudden unexplained partial or complete loss of vision or double vision			√
Breast changes such as breast lumps or breast cancer: pain and tenderness, lumps, nipple discharge		√	
Uterine myoma expulsion or prolapse (fibroid comes out either completely or partially through the Vagina): usually with cramping and increased bleeding from the vagina		√	
Cholestasis (gallbladder problems): jaundice (yellowing of the skin or whites of the eyes), dark urine, light coloured stools		√	
Too much bleeding from the womb: abnormal vaginal bleeding, bleeding that lasts too long, that is too much, or is unexpected	√		
Liver problems: yellowing of the skin or eyes, dark urine, feeling tired, nausea, vomiting,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
generalized swelling, right upper stomach pain or bruising			
Allergic reactions: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue, or throat			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store MYFEMBREE at room temperature between 15°C to 30°C.
- Do not flush unused tablets down the toilet.
- Use the MYFEMBREE 28-count, provided in the 60 cc HDPE bottles with desiccant in 28 days.
- Return unused tablets to the pharmacy or dispose of them in a safety way according to local requirements. The hormonal active compounds in the tablet may have harmful effects if reaching the aquatic environment. These measures will help protect the environment.
- Keep MYFEMBREE out of the reach of children and sight of children.

If you want more information about MYFEMBREE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the distributor and importer's website www.pfizer.ca or by calling 1-800-463-6001.

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