How To Discuss Uterine Fibroid Treatment With an OB/GYN

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Did you know that uterine fibroids, the most common type of benign tumor in patients of reproductive age, affects up to 70% of Caucasian patients and more than 80% of African American patients by the age of 50?[1] Although these non-cancerous tumors of the uterus can be asymptomatic in some patients, others can experience heavy menstrual bleeding that can significantly impact their day-to-day lives.[2-4]

For patients who receive a uterine fibroid diagnosis, there may be a feeling of "what now?", along with a sense of uncertainty when trying to identify the best treatment approach for them. Traditionally, uterine fibroids have been managed by surgery and are the leading reason for hysterectomies performed in the U.S.[2-4] However, several treatment options, including medical management, are available.

Veronica Gillispie-Bell, MD, MS, who is a paid sponsor of AbbVie, is a practicing OB-GYN and section head of women's services at Ochsner Kenner in New Orleans who has dedicated nearly 20 years researching uterine fibroids. She discusses the importance of individualizing treatment plans for patients.

"Patients don't understand that there are several different treatment options," Dr. Gillispie-Bell explains, "so I am very happy to be able to tell them that there are more options beyond suffering and a complete hysterectomy."

The advice she gives uterine fibroid patients ready to have their first conversation about treatment options with a healthcare provider is, "Try to prepare as much as possible beforehand. Do some research and write your questions down prior to your appointment. If possible, bring someone with you because there is a lot of information to retain. Having a family member there to help you remember and process all the information can be very helpful." She continues, "Also, understand that if you see a provider who only offers you one option, then that might not be the best provider for you; you should be offered many options and together should be able to decide on the best plan of action taking into consideration your specific circumstances."

Understanding her patient's treatment goals helps Dr. Gillispie-Bell guide them towards an option. She further states, "treatment is individualized by patient, and all depends on symptoms. Patients should be aware of all treatment options available to them, from the least to most invasive."

Medical treatment options may be used to manage heavy menstrual bleeding associated with fibroids.[5]

ORIAHNN® (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is an oral treatment specifically indicated for heavy menstrual bleeding due to uterine fibroids in premenopausal women. Oriahnn should not be taken for longer than 24 months. It is not known if Oriahnn is safe and effective for children under 18 years of age.[6]

Elagolix, the main ingredient of Oriahnn, decreases the amount of estrogen and progesterone in your body. Lowering these hormones can help lighten heavy periods but can also lead to possible side effects like bone loss. To help manage these side effects, ORIAHNN also contains 2 other ingredients: estradiol (E2) and norethindrone acetate (NETA).

Oriahnn may increase your chances of heart attack, stroke, or blood clots, especially if you are over 35 years of age and smoke, have uncontrolled high blood pressure, high cholesterol, diabetes, and/or are obese.[6] Stop taking Oriahnn and talk to a doctor right away if you have symptoms of a heart attack, stroke, or blood clot.

Please see additional Important Safety Information for Oriahnn below.

Dr. Gillispie-Bell understands that patients may feel overwhelmed or uncertain of what to do after a uterine fibroid diagnosis. "Please know there are treatment options available for heavy menstrual bleeding associated with fibroids. It's important for patients to see a provider who can explain the options available, and the risks associated with each approach. As I tell my patients, it's all about working together to find a treatment option that for works for you."

To learn more about Oriahnn and how to talk to your gynecologist, visit ORIAHNN.com.

Please click to see the Full Prescribing Information, including the Medication Guide.

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ORIAHNN® (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is a prescription medicine used to control heavy menstrual bleeding related to uterine fibroids in women before menopause. It should not be taken for more than 24 months. It is not known if ORIAHNN is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ORIAHNN?

ORIAHNN may cause serious side effects, including:

- Cardiovascular Conditions
  - ORIAHNN may increase your chances of heart attack, stroke, or blood clots, especially if you are over 35 years of age and smoke, have uncontrolled high blood pressure, high cholesterol, diabetes, or are obese. Stop taking ORIAHNN and call your healthcare provider right away or go to the nearest hospital emergency room right away if you have:
    - Leg pain or swelling that will not go away
    - Sudden shortness of breath
    - Double vision, bulging of the eyes, or sudden blindness (partial or complete)
    - Pain or pressure in your chest, arm, or jaw
    - Sudden, severe headache unlike your usual headaches
    - Weakness or numbness in an arm or leg, or trouble speaking
  - Bone Loss (Decreased Bone Mineral Density [BMD])
    - While taking ORIAHNN, your estrogen levels may be low. Low estrogen levels can lead to BMD loss.
    - If you have bone loss on ORIAHNN, your BMD may improve after you stop taking ORIAHNN, but complete recovery may not occur. It is unknown if these BMD changes could increase your risk for broken bones as you age. For this reason, you should not take ORIAHNN for more than 24 months.
    - Your healthcare provider may order an X-ray test called a DXA scan to check your bone mineral density when you start taking ORIAHNN and periodically after you start.
    - Your doctor may advise you to take vitamin D and calcium supplements as part of a healthy lifestyle.
  - Effects on Pregnancy
    - Do not take ORIAHNN if you are pregnant or trying to become pregnant, as it may increase the risk of early pregnancy loss.
    - If you think you may be pregnant, stop taking ORIAHNN right away and call your HCP.

- ORIAHNN can decrease your menstrual bleeding or result in no menstrual bleeding at all, making it hard to know if you are pregnant. Watch for other pregnancy signs like breast tenderness, weight gain, and nausea.
- ORIAHNN does not prevent pregnancy. You will need to use effective methods of birth control while taking ORIAHNN and for 28 days after you stop taking ORIAHNN. Examples of effective methods can include condoms or spermicide, which do not contain hormones.
- Talk to your HCP about which birth control to use during treatment with ORIAHNN. Your HCP may change the birth control you are on before you start taking ORIAHNN.

Do not take ORIAHNN if you:

- Have or have had:
  - A stroke or heart attack
  - A problem that makes your blood clot more than normal
  - Blood circulation disorder
  - Certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
  - Blood clots in your legs (deep vein thrombosis), lungs (pulmonary embolism), or eyes (retinal thrombosis)
  - High blood pressure not well controlled by medicine
  - Diabetes with kidney, eye, nerve, or blood vessel damage
  - Certain kinds of headaches with numbness, weakness, or changes in vision, or have migraine headaches with aura if you are over age 35
  - Breast cancer or any cancer that is sensitive to female hormones
  - Osteoporosis
  - Unexplained vaginal bleeding that has not been diagnosed
  - Liver problems including liver disease
- Smoke and are over 35 years old
- Are taking medicines known as strong OATP1B1 inhibitors that are known or expected to

significantly increase the blood levels of elagolix. Ask your HCP if you are not sure if you are taking this type of medicine.

- Have had a serious allergic reaction to elagolix, estradiol, norethindrone acetate, or any of the ingredients in ORIAHNN. Ask your HCP if you are not sure.
- FD&C Yellow No.5 (tartrazine) is an ingredient in ORIAHNN, which may cause an allergic type reaction such as bronchial asthma in some patients who are also allergic to aspirin.

What should I discuss with my HCP before taking ORIAHNN?

Tell your HCP about all your medical conditions, including if you:

- Have or have had:
  - Broken bones or other conditions that may cause bone problems
  - Depression, mood swings, or suicidal thoughts or behavior
  - Yellowing of the skin or eyes (jaundice) or jaundice caused by pregnancy (cholestasis of pregnancy)
- Are scheduled for surgery. ORIAHNN may increase your risk of blood clots after surgery. Your doctor may advise you to stop taking ORIAHNN before you have surgery. If this happens, talk to your HCP about when to restart ORIAHNN after surgery.
- Are pregnant or think you may be pregnant.
- Are breastfeeding. It is not known if ORIAHNN can pass into your breastmilk. Talk to your HCP about the best way to feed your baby if you take ORIAHNN.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Women on thyroid or cortisol replacement therapy may need increased doses of the hormone.

Keep a list of your medicines with you to show to your HCP and pharmacist when you get a new medicine.

What should I avoid while taking ORIAHNN?

- Avoid grapefruit and grapefruit juice during treatment with ORIAHNN since they may affect the

level of ORIAHNN in your blood, which may increase side effects.

What are the possible side effects of ORIAHNN?

ORIAHNN can cause additional serious side effects, including:

- Suicidal thoughts, suicidal behavior, and worsening of mood. ORIAHNN may cause suicidal thoughts or actions. Call your HCP or get emergency medical help right away if you have any of these symptoms, especially if they are new, worse, or bother you: thoughts about suicide or dying, attempts to commit suicide, new or worse depression or anxiety, or other unusual changes in behavior or mood. Pay attention to any changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings.
- Abnormal liver tests. Call your HCP right away if you have any of these signs and symptoms of liver problems: jaundice, dark, amber-colored urine, feeling tired, nausea and vomiting, generalized swelling, right upper stomach area pain, or bruising easily.
- High blood pressure. You should see your HCP to check your blood pressure regularly.
- Gallbladder problems (cholestasis), especially if you had cholestasis of pregnancy.
- Increases in blood sugar, cholesterol, and fat (triglyceride) levels.
- Hair loss (alopecia). Hair loss and hair thinning can happen while taking ORIAHNN, and it can continue even after you stop taking ORIAHNN. It is not known if this hair loss or hair thinning is reversible. Talk to your HCP if this is a concern for you.
- Changes in laboratory tests, including thyroid and other hormone, cholesterol, and blood clotting tests.

The most common side effects of ORIAHNN include: hot flashes, headache, fatigue, and irregular periods.

These are not all of the possible side effects of ORIAHNN. Tell your HCP if you have any side effect that bothers you or that does not go away. Call your HCP for medical advice about side effects.

Take ORIAHNN exactly as your HCP tells you. The recommended oral dosage of ORIAHNN is one yellow/white capsule in the morning and one blue/white capsule in the evening, with or without food.

This is the most important information to know about ORIAHNN. For more information, talk to your doctor or HCP.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

Please see the Full Prescribing Information, including the Medication Guide.

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[1] Baird D et al. High cumulative incidence of uterine leiomyoma in black and white women: Ultrasound evidence. Am J Obstet Gynecol. 2003;188:100-107.

[2] De La Cruz MS et al. Uterine Fibroids: Diagnosis and Treatment. Am Fam Physician. 2017;95(2):100-107.

[3] Khan A et al. Uterine fibroids: current perspectives. Int J Women's Health. 2014;6:95-114.

[4] ACOG (2019). Uterine Fibroids. https://www.acog.org/patient-resources/faqs/gynecologic-problems/uterine-fibroids. Accessed March 2020.

[5] Alternatives to hysterectomy in the management of leiomyomas. ACOG Practice Bulletin No. 96. American College of Obstetricians and Gynecologist. Obstet Gynecol. 2008; 112:387-400.

[6] ORIAHNN® (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) [Package Insert]. North Chicago, Ill.: AbbVie Inc.

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