

MEDICATION GUIDE
ORIAHNN® (or-ee-ahn)
(elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)
co-packaged for oral use

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, 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)**
 - While you are taking ORIAHNN, your estrogen levels may be low. Low estrogen levels can lead to bone mineral density loss.
 - If you have bone loss on ORIAHNN, your bone density may improve after you stop taking ORIAHNN, but complete recovery may not occur. It is unknown if these bone 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 healthcare provider may advise you to take vitamin D and calcium supplements as part of a healthy lifestyle that promotes bone health. Iron supplements should not be taken at the same time that you take vitamin D and calcium supplements.
- **effects on pregnancy**
 - **Do not take ORIAHNN** if you are trying to become pregnant or are pregnant. It may increase the risk of early pregnancy loss.
 - **If you think you may be pregnant**, stop taking ORIAHNN right away and call your healthcare provider.
 - If you become pregnant while taking ORIAHNN, you are encouraged to enroll in the Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby. Contact the registry as soon as you learn that you are pregnant or ask your healthcare provider to contact the registry for you. You or your healthcare provider can get information and enroll you in the registry by calling 1-833-782-7241 or visiting <https://www.bloompregnancyregistry.com>.
 - 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 signs of pregnancy such as 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 healthcare provider about which birth control to use during treatment with ORIAHNN. Your healthcare provider may change the birth control you were on before you start taking ORIAHNN.

What is ORIAHNN?

ORIAHNN is a prescription medicine used to control heavy menstrual bleeding in premenopausal women (before “change of life” or menopause) with uterine fibroids.

It is not known if ORIAHNN is safe and effective in children under 18 years of age.

Do not take ORIAHNN if you:

- have or have had:
 - stroke or a 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. Your healthcare provider should check any unexplained vaginal bleeding to find out the cause.
- liver problems including liver disease
- smoke and are over 35 years old
- are taking medicines known as OATP1B1 inhibitors that are known or expected to significantly increase the blood levels of elagolix (an ingredient in ORIAHNN). Ask your healthcare provider 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 healthcare provider 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. See the end of this Medication Guide for a complete list of ingredients in ORIAHNN.

Before you take ORIAHNN, tell your healthcare provider about all of 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 healthcare provider may advise you to stop taking ORIAHNN before you have surgery. If this happens, talk to your healthcare provider 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 healthcare provider about the best way to feed your baby if you take ORIAHNN.

Tell your healthcare provider 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.

Know the medicines you take. Keep a list of your medicines with you to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take ORIAHNN?

- Take ORIAHNN exactly as your healthcare provider tells you to take it.
- Your healthcare provider will give you a pregnancy test before you start taking ORIAHNN or will have you start taking ORIAHNN within 7 days after you start your period.
- Take 1 white and yellow ORIAHNN capsule in the morning and 1 white and light blue ORIAHNN capsule in the evening each day.
- Take ORIAHNN at about the same time each morning and evening with or without food.
- If you take too much ORIAHNN, call your healthcare provider or go to the nearest hospital emergency room right away.

If you miss a dose of ORIAHNN (morning or evening capsules):

- Take the missed dose within 4 hours of the time that it was supposed to be taken. Then take the next dose at the usual time.

- If more than 4 hours have passed since you usually take the morning or evening dose, skip the missed dose. Take your next dose at the usual time.
- **Do not take 2 doses** to make up for the missed dose.

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 may cause serious side effects including:

- See “**What is the most important information I should know about ORIAHNN?**”
- **suicidal thoughts, suicidal behavior, and worsening of mood.** ORIAHNN may cause suicidal thoughts or actions. **Call your healthcare provider 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
 - new or worse anxiety
 - 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 healthcare provider right away if you have any of these signs and symptoms of liver problems:**
 - jaundice
 - dark amber-colored urine
 - feeling tired (fatigue or exhaustion)
 - nausea and vomiting
 - generalized swelling
 - right upper stomach area (abdomen) pain
 - bruising easily
- **high blood pressure.** You should see your healthcare provider 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 healthcare provider 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 flushes, headache, fatigue, and irregular periods.

These are not all the possible side effects of ORIAHNN. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ORIAHNN?

- Store ORIAHNN at room temperature between 68°F to 77°F (20°C to 25°C).
- **Do not** keep medicine that is out of date or that you no longer need.
- Dispose of unused medicines through community take-back disposal programs when available. If no community take-back disposal program is available go to www.fda.gov/drugdisposal for information on how to dispose of ORIAHNN the right way.
- **Do not** flush ORIAHNN down the toilet.

Keep ORIAHNN and all medicines out of the reach of children.

General information about the safe and effective use of ORIAHNN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ORIAHNN for a condition for which it was not prescribed. Do not give ORIAHNN to other people,

even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ORIAHNN that is written for health professionals.

What are the ingredients in ORIAHNN?

Yellow/White AM Capsule:

Active ingredient: elagolix, estradiol, norethindrone acetate.

Inactive ingredients: anhydrous sodium carbonate, polyethylene glycol 3350, crospovidone, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, purified water, lactose monohydrate, starch (corn), copovidone, talc, hypromellose, triacetin, and a gelatin capsule shell. The capsule shell contains the following ingredients: FD&C Red #40, FD&C Yellow #5, FD&C Yellow #6, titanium dioxide, gelatin, and printing ink (shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide, and purified water).

Light Blue/White PM Capsule:

Active ingredient: elagolix.

Inactive ingredients: anhydrous sodium carbonate, polyethylene glycol 3350, crospovidone, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, and talc, purified water, and a gelatin capsule shell. The capsule shell contains the following ingredients: FD&C Blue #2, FDA/E172 yellow iron oxide, titanium dioxide, gelatin, and printing ink (shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide, and purified water).

Manufactured by AbbVie Inc. North Chicago, IL 60064

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For more information, go to www.ORIAHNN.com or call 1-844-674-2466.

This Medication Guide has been approved by the U.S. Food and Drug Administration
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