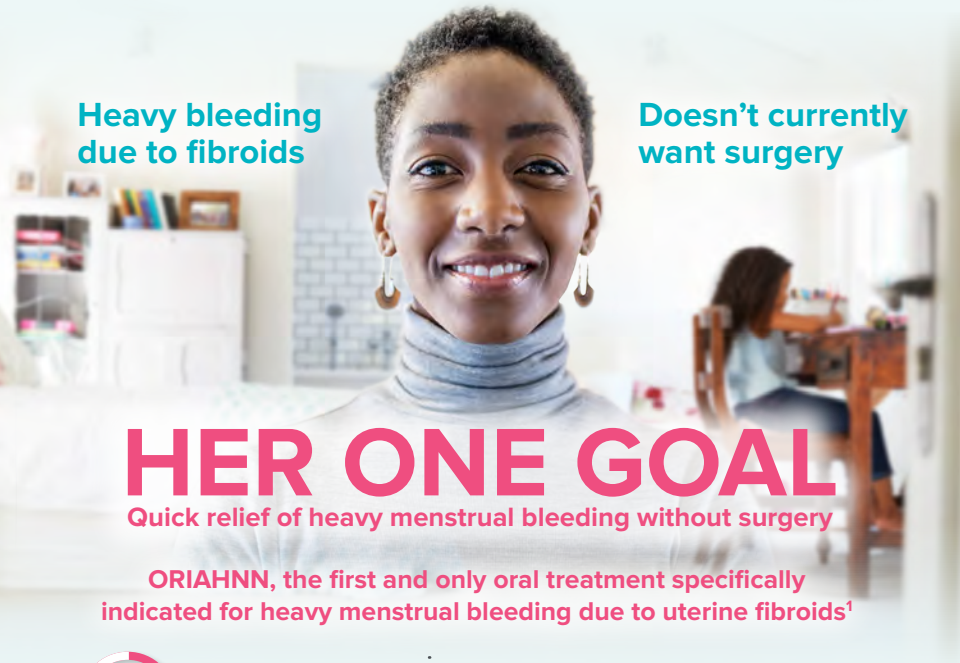
Oriahnn™

elagolix, estradiol and norethindrone acetate capsules and elagolix capsules 300 mg/1 mg/0.5 mg and 300 mg



HER ONE GOAL

Quick relief of heavy menstrual bleeding without surgery

ORIAHNN, the first and only oral treatment specifically indicated for heavy menstrual bleeding due to uterine fibroids[1]

>50% **Average bleeding reduction seen at Month 1[2]**

3 out of 395 women taking ORIAHNN discontinued for fibroid surgery in the 6-month clinical trials[3]

INDICATION[1]

ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

SAFETY CONSIDERATIONS[1]

Estrogen and progestin combinations, including ORIAHNN, 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.

ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke and women with uncontrolled hypertension.

- ORIAHNN is contraindicated in women who are at a high risk of arterial, venous thrombotic, or thromboembolic disorders; who are pregnant; with known osteoporosis; current or history of breast cancer or other hormonally sensitive malignancies; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known anaphylactic reaction, angioedema, or hypersensitivity to ingredients of ORIAHNN; or with concomitant use of organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations.

Please see additional Important Safety Information, including BOXED WARNING on THROMBOEMBOLIC AND VASCULAR EVENTS on pages 7 and 8, and Full Prescribing Information at OriahnnHCP.com or https://rxabbvie.com/pdf/oriahnn_pi.pdf.

"I want relief from my heavy periods, but I don't want surgery right now."

Meet Naomi, age 33

"My dream is to get married and have kids someday. I don't want to risk that choice."

Naomi wants the option to have a baby in the future.

Meet Desiree, age 38

"I'm not ready to jump to a hysterectomy right now. Women like me deserve more options."

Desiree is not ready for a hysterectomy right now.

In a market research analysis of 301 women with heavy bleeding due to fibroids,

~50% self-identify with Naomi or Desiree[4]*

*From a US-based uterine fibroid segmentation survey conducted in 2015 of 301 women with fibroids; this market research analysis assessed demographics and medical history, as well as the impact of uterine fibroids on attitudes and information-seeking behavior, in addition to others.

ORIAHNN controls heavy bleeding due to fibroids

Response rates: Proportion of women who met the primary endpoint at Final Month[1]*

ELARIS UF-1	ELARIS UF-2
ORIAHNN **69%** (n=206)	**ORIAHNN** **77%** (n=189)
Placebo 9% (n=102)	Placebo 11% (n=94)

P<0.001 in both trials.

What did it take to achieve a response?

≥50% (1/2) **AND** **<80 mL** (1/3) **= RESPONDER**

bleeding volume reduction from baseline to Final Month[1]*

bleeding volume at Final Month[1]*

*Final Month is defined as the last 28 days before and including the last treatment visit date or the last dose date.

SAFETY CONSIDERATIONS[1]

- Most common adverse reactions occurring in ≥5% of women receiving ORIAHNN in clinical trials were hot flush, headache, fatigue, and metrorrhagia.

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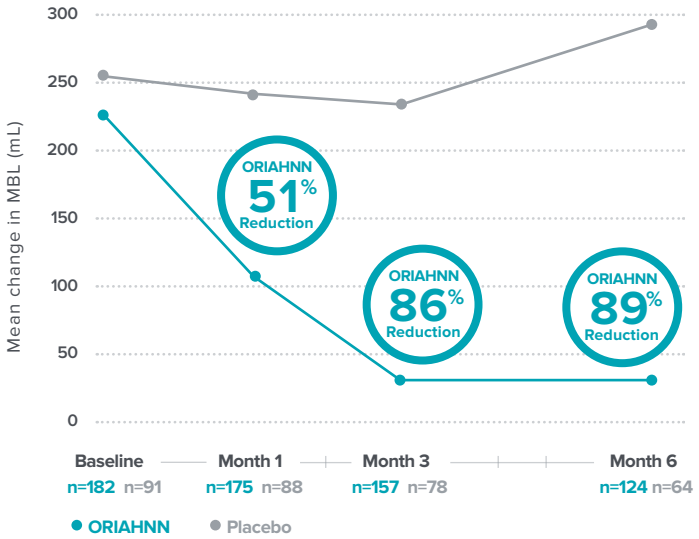
Quick and continued bleeding reduction with ORIAHNN

Over 50% reduction at Month 1 and continued reduction seen at Months 3 and 6[2]

Mean menstrual blood loss (MBL) reduction from baseline in ELARIS UF-2[2]



Results from placebo-controlled ELARIS UF-1 were consistent with those observed in ELARIS UF-2.

Study design[1,5]

- **ORIAHNN** was studied in **2 randomized, double-blind, placebo-controlled Phase 3 studies** (ELARIS UF-1 and UF-2) of 6 months each
- **790 premenopausal women** aged 25-53 who had at least 2 menstrual cycles with >80 mL MBL were randomized to an ORIAHNN BID group, a reference arm,† or a placebo group
  - The reference arm† was included to characterize the impact of E2/NETA on efficacy and safety

ORIAHNN met the primary endpoint and all 6 ranked secondary endpoints in its pivotal trials[5]

BID=twice a day; E2/NETA=estradiol/norethindrone acetate.
†Women in the reference arm received elagolix 300 mg BID.

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ORIAHNN was studied in a broad range of women

Selected patient characteristics at baseline in ELARIS UF-1 and UF-2 (N=790)[1,5-8]

Fibroid Location

- Submucosal (FIGO score 0-3)
- Intramural (FIGO score 4)
- Subserosal (FIGO score 5-8)

Primary Fibroid Volume

Median
36.2 cm^3

Range
1 cm^3-1081.5 cm^3

Uterine Volume

Median
356.5 cm^3

Range
71.6 cm^3-3347.9 cm^3

A uterus that is 14-16 weeks in size is approximately 355 cm^3-460 cm^3.

100% North American population studied

Age range **25-53 years**

Comprised of **68% Black or African American** women

FIGO score=The International Federation of Gynecology and Obstetrics score for classifying leiomyomas.

SAFETY CONSIDERATIONS[1]

- Most common adverse reactions occurring in ≥5% of women receiving ORIAHNN in clinical trials were hot flush, headache, fatigue, and metrorrhagia.

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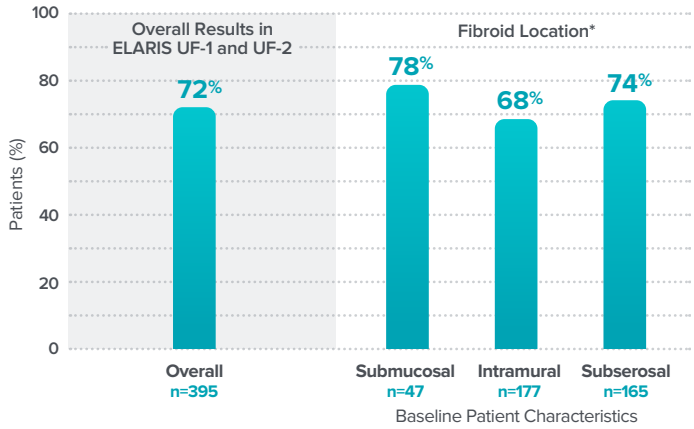
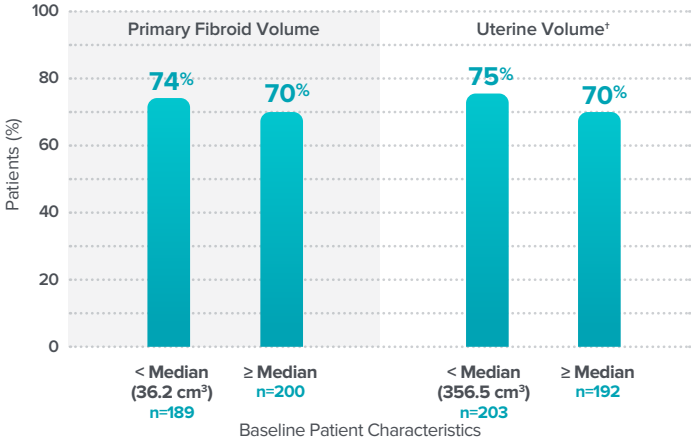
Regardless of her characteristics, ORIAHNN controlled her heavy bleeding

Proportion of women who met the primary endpoint in ELARIS UF-1 and UF-2[6]

The subgroup analyses of the primary endpoint was not a ranked efficacy endpoint and was not powered for statistical significance[5]





*Submucosal: FIGO score 0-3; Intramural: FIGO score 4; Subserosal: FIGO score 5-8.
†A uterus that is 14-16 weeks in size is approximately 355 cm^3-460 cm^3.[7,8]

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Demonstrated safety profile

Adverse reactions, occurring in at least 5% of women receiving ORIAHNN and at a greater frequency than placebo, and their corresponding discontinuation rates in ELARIS UF-1 and UF-2[1,9]

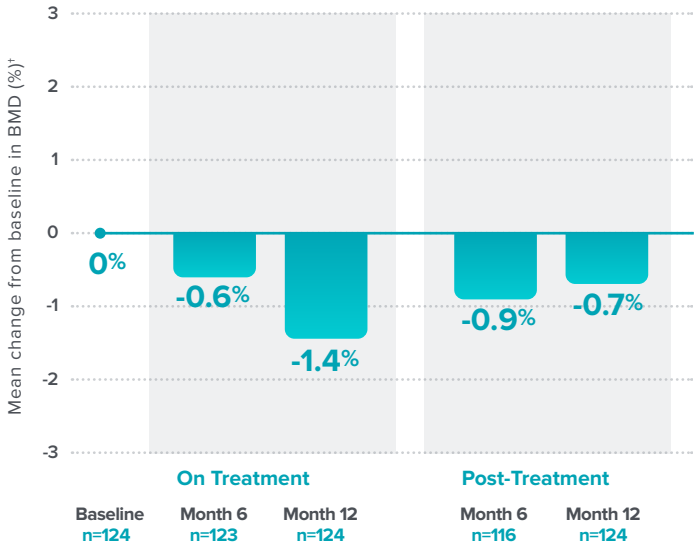
	Incidence		Discontinuation	
	ORIAHNN (n=395)	Placebo (n=196)	ORIAHNN (n=395)	Placebo (n=196)
Hot flush	22%	9%	1%	0.5%
Headache	9%	7%	1%	0.5%
Fatigue	6%	4%	0.3%	0.5%
Metrorrhagia	5%	1%	1%	0%

Discontinuation due to any adverse reaction occurred in 10% of women treated with ORIAHNN and 7% of those who received placebo[1]

ORIAHNN is a combination regimen of elagolix with E2/NETA[1]

Considerations for bone health

Bone mineral density (BMD) change from baseline at lumbar spine in women who received ORIAHNN in ELARIS UF-1, UF-2, and UF-3[1,10*]



Bone mineral density information[1]

- ORIAHNN should be limited to 24 months to limit the impact to bone health
- ORIAHNN may cause a decrease in BMD, which is greater with increasing duration of use and may not be completely reversible after stopping treatment
- Assessment of BMD by DXA is recommended at baseline and periodically thereafter
- Consider discontinuing ORIAHNN if the risk associated with bone loss exceeds the potential benefit of treatment
- ORIAHNN is contraindicated in women with known osteoporosis

DXA=dual-energy X-ray absorptiometry.
*ELARIS UF-3 was a 6-month extension study.
†Data was based off least squares mean.

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An oral treatment designed with her in mind

Packaging shown is not actual size.

1 capsule taken twice a day[1]:

One capsule in the morning
combination of elagolix and E2/NETA

One capsule in the evening
elagolix alone

Use of ORIAHNN should be limited to 24 months[1]

Should be taken at approximately the same time each day[1]

Patients should take missed pills within 4 hours—otherwise skip and take next dose at usual time[1]

Can take with or without food[1]

Before starting treatment, exclude pregnancy OR start within 7 days from the onset of menses[1]

Assessment of BMD by DXA is recommended at baseline and periodically thereafter[1]

NDC code: 0074-1017-56

SAFETY CONSIDERATIONS[1]

- ORIAHNN is contraindicated in women who are at a high risk of arterial, venous thrombotic, or thromboembolic disorders; who are pregnant; with known osteoporosis; current or history of breast cancer or other hormonally sensitive malignancies; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known anaphylactic reaction, angioedema, or hypersensitivity to ingredients of ORIAHNN; or with concomitant use of organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations.

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Schedule a follow-up appointment after starting ORIAHNN to assess how she's doing

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INDICATION[1]

ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

IMPORTANT SAFETY INFORMATION[1]

THROMBOEMBOLIC AND VASCULAR EVENTS

Estrogen and progestin combinations, including ORIAHNN, 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.

ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke and women with uncontrolled hypertension.

CONTRAINDICATIONS

- ORIAHNN is contraindicated in women at a high risk of arterial, venous thrombotic, or thromboembolic disorders; who are pregnant; with known osteoporosis; current or history of breast cancer or other hormonally sensitive malignancies; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known anaphylactic reaction, angioedema, or hypersensitivity to ingredients of ORIAHNN; or with concomitant use of organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations.

WARNINGS AND PRECAUTIONS

Thromboembolic Disorders and Vascular Events

- ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events. Components of ORIAHNN increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at high risk for these events. In general, the risk is greatest among women over 35 years of age who smoke, and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.
- Discontinue ORIAHNN if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs. If feasible, discontinue ORIAHNN at least 4 to 6 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Stop ORIAHNN if there is sudden, unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately.

Bone Loss

- ORIAHNN is contraindicated in women with known osteoporosis. ORIAHNN may cause a decrease in bone mineral density (BMD) in some patients, which is greater with increasing duration of use and may not be completely reversible after stopping treatment.
- The impact of ORIAHNN-associated decreases in BMD on long-term bone health and future fracture risk is unknown. Consider the benefits and risks of ORIAHNN in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss, including those taking medications that may decrease BMD (e.g., systemic or chronic inhaled corticosteroids, anticonvulsants, or proton pump inhibitors).
- Assessment of BMD by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter. Consider discontinuing ORIAHNN if the risk associated with bone loss exceeds the potential benefit of treatment. Limit the duration of use to 24 months to reduce the extent of bone loss.

Hormonally Sensitive Malignancies

- ORIAHNN is contraindicated in women with current or a history of breast cancer and in women at increased risk for hormonally sensitive malignancies, such as those with mutations in BRCA genes.
- The use of estrogen alone and estrogen plus progestin has been reported to result in an increase in abnormal mammograms requiring further evaluation. Surveillance measures, such as breast examinations and regular mammography, are recommended. Discontinue ORIAHNN if a hormonally sensitive malignancy is diagnosed.

Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders

- Depression, depressed mood, and/or tearfulness were reported at a higher incidence in women taking ORIAHNN (3%) compared with placebo (1%) in the Phase 3 clinical trials. Suicidal ideation and behavior, including a completed suicide, occurred in women treated with lower doses of elagolix in clinical trials conducted for a different indication.
- Promptly evaluate patients with depressive symptoms to determine whether the risks of continued therapy outweigh the benefits. Patients with new or worsening depression, anxiety, or other mood changes should be referred to a mental health professional, as appropriate.
- Advise patients to seek immediate medical attention for suicidal ideation and behavior. Reevaluate the benefits and risks of continuing ORIAHNN if such events occur.

Hepatic Impairment and Transaminase Elevations

- ORIAHNN is contraindicated in women with known hepatic impairment or disease.
- Transaminase elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) occurred with ORIAHNN in Phase 3 clinical trials. No pattern in time to onset of these liver transaminase elevations was identified. Transaminase levels returned to baseline within 4 months after peak values in these patients.
- Instruct patients to promptly seek medical attention in case of symptoms or signs that may reflect liver injury, such as jaundice.

Please see additional Important Safety Information, including BOXED WARNING on THROMBOEMBOLIC AND VASCULAR EVENTS on page 8, and Full Prescribing Information at OriahnnHCP.com or https://rxabbvie.com/pdf/oriahnn_pi.pdf.

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IMPORTANT SAFETY INFORMATION[1] (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Elevated Blood Pressure

- ORIAHNN is contraindicated in women with uncontrolled hypertension. Maximum mean increases in systolic blood pressure occurred at Month 5, and a mean maximum increase in diastolic blood pressure occurred at Month 4 in ORIAHNN-treated women, as compared to placebo-treated women.
- For women with well-controlled hypertension, continue to monitor blood pressure and stop ORIAHNN if blood pressure rises significantly. Monitor blood pressure in normotensive women treated with ORIAHNN.

Gallbladder Disease or History of Cholestatic Jaundice

- Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease. For women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, assess the risk-benefit of continuing therapy. Discontinue ORIAHNN if jaundice occurs.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy

- ORIAHNN may delay the ability to recognize the occurrence of a pregnancy because it may reduce the intensity, duration, and amount of menstrual bleeding. Perform pregnancy testing if pregnancy is suspected and discontinue ORIAHNN if pregnancy is confirmed.
- The effect of hormonal contraceptives on the efficacy of ORIAHNN is unknown. Advise women to use non-hormonal contraception during treatment and for 1 week after discontinuing ORIAHNN.

Effects on Carbohydrate and Lipid Metabolism

- ORIAHNN may decrease glucose tolerance and result in increased glucose levels. More frequent monitoring in ORIAHNN-treated women with prediabetes and diabetes may be needed.
- In women with preexisting hypertriglyceridemia, estrogen therapy may be associated with elevations of plasma triglycerides leading to pancreatitis. Use of elagolix is associated with increases in total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and serum triglycerides. Monitor lipid levels and consider discontinuing ORIAHNN if hypercholesterolemia or hypertriglyceridemia worsens.

Alopecia

- In Phase 3 clinical trials, more women experienced alopecia, hair loss, and hair thinning with ORIAHNN (3.5%) compared to placebo (1.0%). In almost one-third of affected ORIAHNN-treated women, alopecia was the reason for discontinuing treatment. No specific pattern was described. In the majority of these women, hair loss was continuing when ORIAHNN was stopped. Whether the hair loss is reversible is unknown. Consider discontinuing ORIAHNN if hair loss becomes a concern.

Effect on Other Laboratory Results

- The use of estrogen and progestin combinations may raise serum concentrations of binding proteins (e.g., thyroid-binding globulin, corticosteroid-binding globulin), which may reduce the free thyroid or corticosteroid hormone levels. Patients with hypothyroidism and hypoadrenalism may require higher doses of thyroid hormone or cortisol replacement therapy, respectively.
- The use of estrogen and progestin may also affect the levels of sex hormone-binding globulin, coagulation factors, lipids, and glucose.

RISK OF ALLERGIC REACTIONS DUE TO THE INACTIVE INGREDIENT (FD&C YELLOW NO. 5)

- ORIAHNN contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

- Most common adverse reactions occurring in ≥5% of women receiving ORIAHNN in clinical trials were hot flush, headache, fatigue, and metrorrhagia.

These are not all of the possible side effects of ORIAHNN.

Safety and effectiveness of ORIAHNN in pediatric patients have not been established.

Please see accompanying Full Prescribing Information at OriahnnHCP.com or https://rxabbvie.com/pdf/oriahnn_pi.pdf.

*Program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be eligible to participate in program. Available to patients between the ages of 18-63 with commercial prescription insurance coverage who meet eligibility criteria. Eligibility: Patients must be diagnosed with heavy menstrual bleeding related to uterine fibroids, have a valid prescription for ORIAHNN and participate in a commercial insurance plan that has denied or not yet made a formulary decision for ORIAHNN. Once the patient's insurance plan has made a formulary decision and established a process for reviewing coverage requests for ORIAHNN, continued eligibility for the program requires the submission of a Prior Authorization prior to the next scheduled dose and appeal of the coverage denial within 180 days. Program provides ORIAHNN™ at no charge to patients for up to 2 years or until they receive insurance coverage approval, whichever occurs earlier. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage.

†Terms and Conditions apply. This benefit covers ORIAHNN™ (elagolix, estradiol and norethindrone acetate capsules; elagolix capsules). Eligibility: Available to patients with commercial prescription insurance coverage for ORIAHNN who meet eligibility criteria. Copay assistance program is not available to patients receiving prescription reimbursement under any federal, state, or government-funded insurance programs (for example, Medicare [including Part D], Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs programs) or where prohibited by law or by the patient's health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state, or government-funded healthcare program, patient will no longer be able to use the Oriahnn Complete Savings Card and patient must call Oriahnn Complete at 1-800-ORIAHNN (1-800-674-2466) and stop use of the copay card. Patients residing in or receiving treatment in certain states may not be eligible. Patients may not seek reimbursement for value received from Oriahnn Complete including the copay card from any third-party payers. Offer subject to change or discontinuance without notice. Restrictions including monthly maximums may apply. This is not health insurance.

References: 1. ORIAHNN [package insert]. North Chicago, IL: AbbVie Inc. **2.** Data on file. ABVRRTI70254. **3.** Data on file. ABVRRTI70090. **4.** Data on file. ABVRRTI70340. **5.** Schlaff WD, Ackerman RT, Al-Hendy A, et al. Elagolix for heavy menstrual bleeding in women with uterine fibroids. *N Engl J Med*. 2020;382(4):328-340. **6.** Al-Hendy A, Simon J, Hurtado S, et al. Effect of fibroid location and size on efficacy of elagolix: results from phase 3 clinical trials. Oral abstract presented at: American Society for Reproductive Medicine 2019 Scientific Congress and Expo; October 12-16, 2019; Philadelphia, PA. **7.** Sheth SS, Hajari AR, Lulla CP, Kshirsagar D. Sonographic evaluation of uterine volume and its clinical importance. *J Obstet Gynaecol Res*. 2017;43(1):185-189. **8.** Harb TS, Adam RA. Predicting uterine weight before hysterectomy: ultrasound measurements versus clinical assessment. *Am J Obstet Gynecol*. 2005;193(6):2122-2125. **9.** Data on file. ABVRRTI70146. **10.** Data on file. ABVRRTI70690.

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Help your patients start and stay on track with their prescribed ORIAHNN treatment plan

Enrollment in Oriahnn Complete offers resources to help your patient access her medication

Oriahnn™ COMPLETE

Access to ORIAHNN for $0 while coverage is being established for eligible commercially insured patients*

Access Specialists who can educate your office about insurance processes and requirements to help patients access ORIAHNN in a timely manner

ORIAHNN for as little as $5† per month for eligible commercially insured patients using the Oriahnn Complete Savings Card

*Eligibility restrictions apply. Please see full eligibility requirements on page 8.
†Terms and Conditions apply. Please see full Terms and Conditions on page 8.

Start your patients today with the Oriahnn Complete Enrollment and Prescription Form by asking your Sales Representative or visiting OriahnnHCP.com

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