Orilissa® COMPLETE

Enrollment and Prescription Form

OE-030122-A03 December 2021

1. Once completed, please fax this form to Orilissa® Complete at 1-833-674-5477.
2. Give your patient the accompanying Welcome Sheet.

Questions? Call 1-800-ORILISSA (1-800-674-5477).

All fields marked with an asterisk (*) are required. The HCP and the patient or legally authorized person should fill out this form completely before leaving the office.

1 Patient Information*

To be completed by patient or legally authorized person:

Patient First Name: _____ Last Name: _____ Date of Birth: _____

Patient Address: _____ City: _____ State: _____ ZIP: _____

Phone # (mobile preferred): _____ Patient Email: _____

☐ I consent to receive automated and recurring text messages from AbbVie, including service updates, medication reminders and marketing messages, to the above mobile number. Message and data rates may apply. My consent is not a condition of receiving goods or services. I can reply HELP for help. I can text STOP to unsubscribe at any time. **View full Terms and conditions at www.abbv.ie/os-terms.**

Best time to call (Monday-Friday): ☐ Anytime ☐ Morning ☐ Afternoon ☐ Evening Orilissa Complete will confirm shipping details when they call.

☐ Check here if an interpreter is needed.

By enrolling, you may have access to your own Nurse Ambassador. Nurse Ambassadors are provided by AbbVie and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals. To learn about AbbVie's privacy practices and your privacy choices, visit www.abbvie.com/privacy.html.

☐ I would like to receive news and updates about AbbVie's products, clinical trials, research opportunities, programs, and other information that may be of interest to me

2 Insurance Information*

☐ Check box if your doctor's office will copy and attach insurance cards

Beneficiary/Cardholder Name: _____

Medical Insurance: _____

Medical Insurance ID #: _____ Group #: _____

Prescription Insurance: _____

RX Group #: _____ RX ID #: _____

RX Bin #: _____ RX PCN #: _____

For Healthcare Provider (HCP) Use Only

3 Diagnosis*

☐ Moderate to severe pain associated with endometriosis

4 Prescriber Information

HCP First Name*: _____ Last Name*: _____ NPI #*: _____

HCP Address*: _____ City*: _____ State*: _____ ZIP*: _____

Office Contact Name: _____ Office Phone #*: _____

Office Contact Email: _____ Office Fax #: _____

Preferred method of contact: ☐ Phone ☐ Fax

5 Orilissa Complete Prescription—Stamp Signatures Cannot Be Accepted

28-day Free Trial Start (for clinically appropriate patients)†

Select dose and sign below to ensure your patient receives a free 28-day trial to determine if ORILISSA is the right treatment for her.

Choose one:
☐ ORILISSA 150 mg tablets–1 tablet PO QD–dispense 1-month supply (28 tablets)
☐ ORILISSA 200 mg tablets–1 tablet PO BID–dispense 1-month supply (56 tablets)

Prescriber's Signature: _____

Date: ___/___/___ **NO REFILLS**

To Continue on Treatment‡

Select dose and sign below in the event there is a **delay or denial in your patient's commercial insurance**. By signing, you agree to continue to pursue insurance coverage for ORILISSA for as long as the patient remains on therapy, as described in the program terms and conditions contained on page 2.

Choose one:
☐ ORILISSA 150 mg tablets–1 tablet PO QD–dispense 1-month supply (28 tablets)
☐ ORILISSA 200 mg tablets–1 tablet PO BID–dispense 1-month supply (56 tablets)

Prescriber's Signature: _____

Date: ___/___/___ Refills: _____ Restrictions per state may apply

SIGN HERE§

Please review prescriber certification statement on page 2 before signing.

IMPORTANT INFORMATION: By submitting this form, you are referring the above patient to AbbVie's patient support program to determine eligibility and receive support related to an AbbVie product. AbbVie, its affiliates, collaborators, and agents will use the information collected about you and your patient to provide the patient support and perform research and analytics, on a de-identified basis, for management of the program. For more information about the categories of personal Information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html. Please share this information with your patient.

Please see Important Safety Information on the following page.
Please see Full Prescribing Information at http://www.rxabbvie.com/pdf/orilissa_pi.pdf.

Orilissa® elagolix tablets 150 mg 200 mg

INDICATION

ORILISSA® (elagolix) is indicated for the management of moderate to severe pain associated with endometriosis. Limit the duration of use based on the dose and coexisting condition.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ORILISSA is contraindicated in women who are pregnant (exposure to ORILISSA early in pregnancy may increase the risk of early pregnancy loss), in women with known osteoporosis or severe hepatic impairment, in women taking organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations, and in women with known hypersensitivity reaction to ORILISSA or any of its inactive components. Reactions have included anaphylaxis and angioedema.

WARNINGS AND PRECAUTIONS

Bone Loss

- ORILISSA causes a dose-dependent decrease in bone mineral density (BMD), which is greater with increasing duration of use and may not be completely reversible after stopping treatment.
- The impact of ORILISSA-associated decreases in BMD on long-term bone health and future fracture risk is unknown. ORILISSA is contraindicated in women with known osteoporosis. Consider assessment of BMD in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss.
- Limit the duration of use to reduce the extent of bone loss.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy

- Women who take ORILISSA may experience a reduction in the amount, intensity, or duration of menstrual bleeding, which may reduce the ability to recognize the occurrence of pregnancy in a timely manner. Perform pregnancy testing if pregnancy is suspected, and discontinue ORILISSA if pregnancy is confirmed.

Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders

- Suicidal ideation and behavior, including one completed suicide, occurred in subjects treated with ORILISSA in the endometriosis clinical trials.
- ORILISSA users had a higher incidence of depression and mood changes compared to placebo and ORILISSA users with a history of suicidality or depression had an increased incidence of depression. 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 ORILISSA if such events occur.

Hepatic Transaminase Elevations

- In clinical trials, dose-dependent elevations of serum alanine aminotransferase (ALT) at least 3 times the upper limit of the reference range occurred with ORILISSA.
- Use the lowest effective dose and instruct patients to promptly seek medical attention in case of symptoms or signs that may reflect liver injury, such as jaundice.
- Promptly evaluate patients with elevations in liver tests to determine whether the benefits of continued therapy outweigh the risks.

Interactions with Hormonal Contraceptives

- Advise women to use effective non-hormonal contraceptives during treatment and for 28 days after discontinuing ORILISSA.
- Coadministration of ORILISSA 200 mg twice daily with an estrogen-containing contraceptive is not recommended because of the potential for increased estrogen-associated risks including thromboembolic disorders and vascular events. Coadministration of ORILISSA with an estrogen-containing contraceptive is expected to reduce the efficacy of ORILISSA.
- Coadministration with progestin-containing oral contraceptives may reduce the efficacy of the contraceptive. The effect of progestin-only contraceptives on the efficacy of ORILISSA is unknown. Coadministration of ORILISSA with progestin-containing intrauterine contraceptive systems has not been studied.

ADVERSE REACTIONS

- The most common adverse reactions (>5%) in clinical trials included hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions, and mood changes.

These are not all the possible side effects of ORILISSA.

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

Please see Full Prescribing Information at http://www.rxabbvie.com/pdf/orilissa_pi.pdf.

Orilissa Complete TERMS AND CONDITIONS

†The ORILISSA® (elagolix) free trial provides a single 28-day trial supply of ORILISSA at no cost to new patients residing in the United States with a valid prescription for an FDA-approved indication of ORILISSA and who enroll in ORILISSA Complete. The trial is intended solely to allow new patients not currently taking ORILISSA to determine with their healthcare provider whether ORILISSA is right for them. There is no obligation to continue use of ORILISSA after the trial has concluded and this program does not guarantee insurance coverage. Eligible patients are limited to one 28-day trial supply and may not re-enroll. The ORILISSA trial supply will be dispensed only through an AbbVie-authorized pharmacy to the patient's home address and may not be sold or further distributed. No claims for payment may be submitted to any third-party insurance plan for product dispensed by program. AbbVie reserves the right to change or discontinue the trial at any time without notice. The trial is not health insurance and is not a discount, coupon, rebate, or financial assistance program. Limitations may apply.

‡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 endometriosis, have a valid prescription for ORILISSA®, and participate in a commercial insurance plan that has denied or not yet made a formulary decision for ORILISSA. Once the patient's insurance plan has made a formulary decision and established a process for reviewing coverage requests for ORILISSA, 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 ORILISSA 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.

§**Prescriber Certification:** I certify that ORILISSA is medically necessary and that the diagnosis and other information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed ORILISSA to the previously identified patient, and that I provided the patient with a description of the Orilissa Complete patient support program. I authorize Orilissa Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy. I understand that the no-charge resource through Orilissa Complete may support patients during the first month on treatment. I certify that I will not seek reimbursement from any third-party payer for any no-charge product dispensed by an AbbVie-authorized pharmacy.

Orilissa®
elagolix tablets 150 mg 200 mg

Welcome to Orilissa® Complete!

Starting a medication can raise a lot of questions. That's why we're here to help whenever you may need us.

Wondering what's next?

You may receive a call from Orilissa Complete if additional insurance information is needed. To get your medication as soon as possible, please pick up our call.

We'll help you:

1. Understand your insurance coverage for ORILISSA.
2. Navigate the steps needed to get your medication.
3. Find possible ways to save on future ORILISSA refills. (You could pay as little as $5 a month* for it!)

Orilissa® COMPLETE

You could **save on your prescription.**
Request an Orilissa Complete Savings Card.
Call 1-800-ORILISSA

Please see Important Safety Information and accompanying Consumer Brief Summary, and discuss with your doctor.

Orilissa®
elagolix tablets 150 mg 200 mg

Request personalized, one-on-one support from an Orilissa Complete Nurse Ambassador,† who is committed to answering your questions about ORILISSA and helping you understand your treatment. Call 1-800-674-5477, Monday through Friday, 8 AM–8 PM ET.

*See Terms and Conditions on the reverse side.
†Nurse Ambassadors are provided by AbbVie and do not work under the direction of your healthcare professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

The categories of personal information collected in the Enrollment Form include contact, insurance, prescription, and medical history information. The personal information collected will be used to provide and manage the Orilissa Complete program and to perform research and analytics on a de-identified basis. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit www.abbvie.com/privacy.html

Orilissa® COMPLETE

Please see Important Safety Information on the following page.

Please see Full Prescribing Information, including Medication Guide, at http://www.rxabbvie.com/pdf/orilissa_pi.pdf and discuss with your doctor.

Orilissa®
elagolix tablets 150 mg 200 mg

USE

ORILISSA® (elagolix) is a prescription medicine used to treat moderate to severe pain associated with endometriosis. It is not known if ORILISSA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

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

ORILISSA may cause serious side effects, including:

- **Bone Loss (decreased Bone Mineral Density [BMD])** While you are taking ORILISSA, your estrogen levels will be low. This can lead to BMD loss. If you have bone loss on ORILISSA, your BMD may improve after stopping ORILISSA, but may not recover completely. It is unknown if these bone changes could increase your risk for broken bones as you age. For this reason, your healthcare provider (HCP) may limit the length of time you take ORILISSA. Your HCP may order a DXA scan to check your BMD.
- **Effects on Pregnancy**
  Do not take ORILISSA if you are trying to become or are pregnant, as your risk for early pregnancy loss may increase. **If you think you are pregnant**, stop taking ORILISSA right away and call your HCP. ORILISSA may change your menstrual periods (irregular bleeding or spotting, a decrease in menstrual bleeding, or no 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. ORILISSA does not prevent pregnancy. You will need to use effective hormone-free birth control (such as condoms or spermicide) while taking ORILISSA and for 28 days after stopping ORILISSA. Birth control pills that contain estrogen may make ORILISSA less effective. It is unknown how well ORILISSA works while on progestin-only birth control.

Do not take ORILISSA if you:

- Are pregnant, have osteoporosis, have severe liver disease, are taking medicines called organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase the blood levels of elagolix, the active ingredient in ORILISSA (ask your HCP if you are not sure if you are taking one of these medicines), or have had a serious allergic reaction to ORILISSA or any of the ingredients in ORILISSA. See the end of the Medication Guide for a complete list of ingredients in ORILISSA. Ask your HCP if you are not sure.

What should I tell my HCP before taking ORILISSA?

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

- Have or have had broken bones or other conditions that may cause bone problems; have or have had depression, mood problems, or suicidal thoughts or behavior; have liver problems; think you may be pregnant; or are breastfeeding or plan to be. It is unknown if ORILISSA passes into breast milk. Talk to your HCP about the best way to feed your baby if you take ORILISSA.

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

Especially tell your HCP if you take birth control that contains hormones. Your HCP may advise you to change your method of birth control.

What are the possible side effects of ORILISSA?

ORILISSA can cause serious side effects including:

- **Suicidal thoughts, actions, or behavior, and worsening of mood. 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. You or your caregiver should 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**: yellowing of the skin or the whites of the eyes (jaundice), dark amber-colored urine, feeling tired, nausea and vomiting, generalized swelling, right upper stomach area pain, or bruising easily.

The most common side effects of ORILISSA include: hot flashes and night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression, and mood changes.

These are not all of the possible side effects of ORILISSA. This is the most important information to know about ORILISSA. For more information, talk to your HCP.

Take ORILISSA exactly as your HCP tells you. Tell your HCP if you have any side effect that bothers you or that does not go away. Call your doctor for medical advice about side effects.

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.

Terms and Conditions apply. This benefit covers ORILISSA® (elagolix). Eligibility: Available to patients with commercial prescription insurance coverage for ORILISSA 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 Orilissa Complete Savings Card and patient must call Orilissa Complete at 1-800-ORILISSA 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 ORILISSA, 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.

Please see Full Prescribing Information, including Medication Guide, at http://www.rxabbvie.com/pdf/orilissa_pi.pdf and discuss with your doctor.

Orilissa®
elagolix tablets 150 mg 200 mg