



What is ORILISSA?



How it works
& experience



What are possible
side effects?



How do I start
taking ORILISSA?



Savings &
support



Use & Important
Safety Information

MAKE THE MOVE TO **ORILISSA** TOGETHER

Review this guide with your patients to help them understand their ORILISSA treatment plan and make an informed start together.

WHAT IS ORILISSA?

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.

SAFETY CONSIDERATIONS

Do not use ORILISSA if you are pregnant, have osteoporosis or severe liver disease, take 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), or have had a serious allergic reaction to ORILISSA or any of the ingredients in ORILISSA. ORILISSA does not prevent pregnancy. It may alter your period, so watch for other signs of pregnancy. Stop taking ORILISSA if you become pregnant. Ask about proper birth control, as some may affect how ORILISSA works. ORILISSA may affect how some birth control works. ORILISSA can cause serious side effects, including bone loss, abnormal liver tests, suicidal thoughts or behaviors, and worsening mood. Talk to your healthcare provider right away if you notice changes such as jaundice, dark amber-colored urine, suicidal thoughts or actions, depression, or worsening mood.



1 Please see Use and additional Important Safety Information on page 7, and full Prescribing Information at rxabbvie.com/pdf/orilissa_pi.pdf.



What is ORILISSA?

ORILISSA is a pill that's clinically proven to help relieve endometriosis pain. It's not a painkiller, or injection, surgery, or birth control, and it does not contain hormones.

ORILISSA is proven to reduce the 3 most common types of endometriosis pain:

- 1 PAINFUL PERIODS
- 2 PELVIC PAIN IN BETWEEN PERIODS
- 3 PAIN WITH SEX*

*Only the ORILISSA 200 mg twice-daily dose was proven to work for pain with sex.

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How does ORILISSA work?

Estrogen fuels painful lesions to grow in women with endometriosis. Each dose of ORILISSA dials down estrogen to a different level.

Lowering estrogen levels can help manage endometriosis pain.

How do we know ORILISSA works?

ORILISSA was studied in the largest endometriosis clinical trial program to date.

The program, made up of two 6-month clinical studies, showed that ORILISSA reduces endometriosis pain. It studied the 2 doses of ORILISSA (150 mg once daily and 200 mg twice daily) against placebo in:

1686 WOMEN

AGES 18-49

WITH MODERATE TO SEVERE ENDO PAIN



As of October 2020,
60,000 women and counting
have been prescribed ORILISSA.

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 **Orilissa**[®]
elagolix tablets 150 mg
200 mg



What are the possible side effects of ORILISSA?

Because ORILISSA treats endometriosis pain by lowering estrogen, there are possible related side effects you may experience. Let's review some of these side effects now.

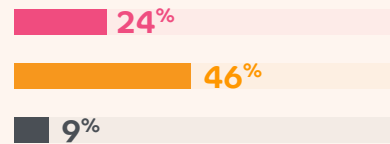
Most common side effects reported by women in the clinical trials:

- ORILISSA 150 mg once daily (n=475)
- ORILISSA 200 mg twice daily (n=477)
- Placebo (n=734)

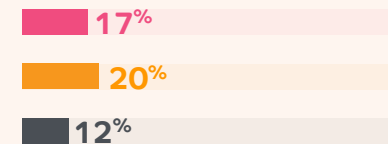
Keep in mind that about 10% or less of the women in the clinical trials stopped taking ORILISSA due to side effects.*†



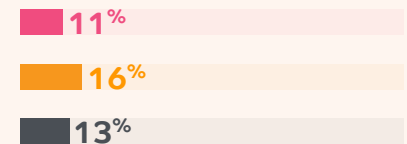
Hot flash



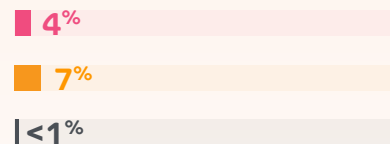
Headache



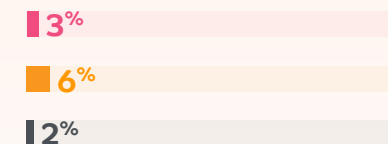
Nausea



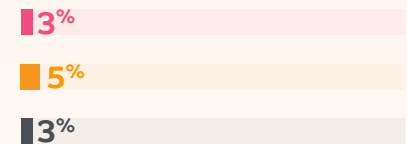
Amenorrhea (absence of periods)



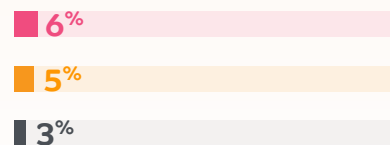
Depressed mood, depression, depressive symptoms, and/or tearfulness



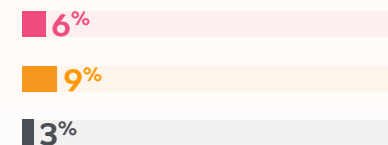
Anxiety



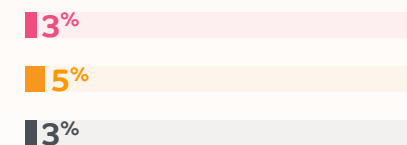
Mood altered, mood swings (mood changes)



Insomnia (trouble sleeping)



Arthralgia (joint pain)



The most common serious adverse events reported in the clinical studies included appendicitis (0.3%), abdominal pain (0.2%), and back pain (0.2%).

These are not all the possible side effects of ORILISSA. Always tell your gynecologist if you have any side effect that bothers you or does not go away.

*5.5% taking ORILISSA 150 mg once daily and 9.6% taking ORILISSA 200 mg twice daily stopped treatment because of side effects, compared with 6% taking placebo.

†0.2% of women treated with ORILISSA 150 mg once daily and 0.2% of women treated with ORILISSA 200 mg twice daily discontinued therapy due to serious adverse reactions compared with 0.5% of those given placebo.



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How do I start taking ORILISSA?

Now that we have agreed on your treatment plan with ORILISSA, it is important to understand how to take your prescribed dose.



ORILISSA 150 mg: One pill taken once a day, at about the same time each day, with or without food



ORILISSA 200 mg: One pill taken twice a day, for a total of 400 mg a day, at about the same time each day, with or without food

Pills are not shown actual size.

Before starting treatment with ORILISSA:

- Review the [Important Safety Information](#) and additional considerations below
- Verify you are not pregnant, or start within 7 day after your period begins
- Discuss an effective method of non-hormonal birth control to use during your treatment with ORILISSA and for 28 days after you stop treatment
- Birth control pills that contain estrogen may make ORILISSA less effective. It's not known how well ORILISSA will work while you're taking progestin-only birth control
- Discontinue ORILISSA if pregnancy occurs. There is a pregnancy registry that monitors outcomes in women who become pregnant while treated with ORILISSA. Enroll by calling 1-833-782-7241



Make your follow-up appointments now—one in 4-6 weeks and another in 3 months.

SAFETY CONSIDERATIONS

ORILISSA can cause serious side effects, including bone loss, abnormal liver tests, suicidal thoughts or behaviors, and worsening mood. Talk to your healthcare provider right away if you notice changes such as jaundice, dark amber-colored urine, suicidal thoughts or actions, depression, or worsening mood.



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The resources you need, when you need them

Orilissa[®] COMPLETE



You can get help navigating insurance

An Orilissa[®] Complete Insurance Specialist can help you understand your insurance and help you identify the next steps to get your medication.



You may pay \$5/month*

If you are a commercially insured patient, you may pay as little as \$5 a month* with the Orilissa Complete Savings Card.



One-on-one support

You can also request personalized, one-on-one support from a Nurse Ambassador,[†] who is committed to answering your questions about ORILISSA and helping you understand your treatment.



Orilissa Complete can help find ways for you to save.
Visit ORILISSA.com/Sign-Up or call **1-800-ORILISSA (1-800-674-5477)**.

*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 (1-800-674-5477) 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 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.

[†]Nurse Ambassadors do not give medical advice and will direct you to your healthcare professional for any treatment-related questions.

 **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.

Please see full Prescribing Information at rxabbvie.com/pdf/orilissa_pi.pdf.

