



ORILISSA
IS THE ONLY
FDA-APPROVED PILL

CLINICALLY PROVEN TO RELIEVE MODERATE TO SEVERE ENDOMETRIOSIS PAIN

WHAT IS ORILISSA?

ORILISSA 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 under 18 years of age.

SAFETY CONSIDERATIONS

Do not use ORILISSA if you are or may be pregnant, have osteoporosis or severe liver disease, or take medicines such as cyclosporine or gemfibrozil. 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 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.

Please see additional Important Safety Information on pages 14-15.

Please see accompanying Full [Prescribing Information](#), including Medication Guide, and discuss with your doctor.

 **Orilissa**[®]
elagolix tablets 150 mg
200 mg
Made for endo pain



PROVEN IN CLINICAL STUDIES

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

1686
WOMEN

AGES
18 TO 49

WITH
MODERATE
TO SEVERE
ENDO PAIN

ORILISSA was proven to relieve 3 common types of endo pain:

- 1 Painful periods
- 2 Pelvic pain in between periods
- 3 Pain with sex‡

†Evaluated in two 6-month clinical trials—952 women were treated with ORILISSA (475 with 150 mg once daily and 477 with 200 mg twice daily) and 734 were treated with placebo.

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

When to expect feeling relief from endo pain:

ORILISSA starts working in the body to lower estrogen after about 24 hours. However, pain relief will take longer. In the clinical studies, ORILISSA was proven to provide relief at 3 months.

Hear what women who have taken ORILISSA are saying about their experiences at [ORILISSA.com/Stories](https://www.orilissa.com/Stories)

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DISCOVER ORILISSA® (elagolix)

ORILISSA is not a painkiller, injection, or birth control. It's a pill specifically proven to reduce moderate to severe endometriosis pain.

Doctors have already prescribed it to over 50,000 women.*

*As of June 2020.

We're so glad you want more info about ORILISSA. Take a look through this brochure, then ask your gynecologist if ORILISSA could be right for you.

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Visit [ORILISSA.com/Home](https://www.orilissa.com/Home) to explore more about ORILISSA.

HOW ORLISSA[®] (elagolix) WORKS

ORLISSA is made for women with moderate to severe endometriosis pain.

It's a pill that works by dialing down estrogen.



ESTROGEN IS A HORMONE THAT'S NATURALLY PRODUCED BY YOUR BODY



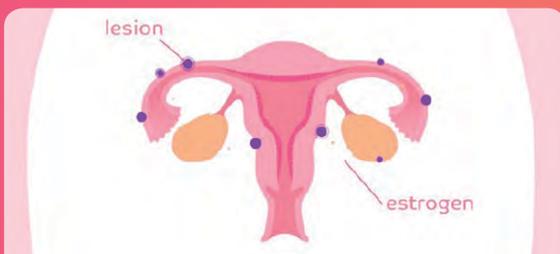
ESTROGEN FUELS THE PAINFUL ENDOMETRIOSIS LESIONS TO GROW



ORLISSA COMES IN 2 DOSES, EACH OF WHICH LOWERS ESTROGEN TO A DIFFERENT LEVEL

Lower estrogen levels can help manage endo pain.

Watch the video to see ORLISSA in action!



VISIT [ORLISSA.COM/HOW](https://www.orilissa.com/how)

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ORLISSA does not prevent pregnancy. It may alter your period, so watch for other signs of pregnancy. Stop taking ORLISSA if you become pregnant. Ask about proper birth control, as some may affect how ORLISSA works.

START MANAGING YOUR ENDO PAIN

ORLISSA is a daily pill—available in 2 doses:

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

ORLISSA 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

Your gynecologist will recommend the lowest effective dose based on your symptoms and treatment goals. Both the pain relief and any side effects you may experience could be different, depending on the dose you take and how your body responds.



It's important to **take ORLISSA every day**, exactly as your gynecologist prescribed—even if you're feeling better.



It does not contain hormones and does not prevent pregnancy.

Get more details on how to take ORLISSA, or what to do if you forget a dose, at [ORLISSA.com/about/how-to-take-ORLISSA](https://www.orilissa.com/about/how-to-take-ORLISSA)

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UNDERSTANDING POSSIBLE SIDE EFFECTS

Because ORILISSA treats endometriosis pain by lowering estrogen, there are possible related side effects you may experience.

The most common side effects of ORILISSA include:

hot flashes or night sweats, headache, nausea, difficulty sleeping, absence of periods, anxiety, joint pain, depression, and mood changes.

In the ORILISSA clinical studies, about 10% or less stopped taking ORILISSA due to side effects.*†

How many women in the clinical trials experienced hot flashes or night sweats?



Well, about 1 out of 4 women taking ORILISSA 150 mg and about 2 out of 4 women taking ORILISSA 200 mg experienced hot flashes or night sweats.

Of these women, 94% reported that the hot flashes they had were mild or moderate (303 of 324 women).‡ Less than 2% of women stopped taking ORILISSA because of hot flashes.§

ORILISSA can cause the following serious side effects:

• Suicidal thoughts, suicidal behavior, and worsening of mood. We understand how serious



this is, so we want to tell you a bit more about what happened in the clinical trials and why this warning exists. See, out of the 2090 women studied,¶ 4 experienced

suicidal thoughts. 2 of these women stopped taking ORILISSA because of this. One woman from the clinical trials committed suicide. Investigators determined that she was experiencing life stressors. We want you to know about it because you should have all the facts when deciding if a medication is right for you.

- **Your safety is important.** Share any other conditions you have or have had, including depression, and talk about any mood problems or suicidal thoughts or

behavior before starting ORILISSA. Call a doctor right away if you have any of these symptoms: thoughts of suicide or dying, try 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.

- Women with depression are not restricted from taking ORILISSA, but it's important to call your doctor if these symptoms appear or worsen while taking ORILISSA. In the ORILISSA clinical trial program, 19% of women had a history of depression and 13% were taking antidepressants when they entered the study.¶

- **Abnormal liver tests.** Call your doctor right away if you have any of these signs and symptoms of liver problems: yellowing of the skin or whites of the eyes (jaundice), dark amber-colored urine, feeling tired (fatigue or exhaustion), nausea and vomiting, generalized swelling, right upper stomach area (abdomen) pain, bruising easily.



These are not all the possible side effects of ORILISSA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

*These women were in the ORILISSA clinical trials and had all taken ORILISSA for 6 months.

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

‡Mild/moderate were definitions used by the clinical researcher to rate the severity of each side effect. Mild was defined as temporary and easily tolerated. Moderate was defined as causing discomfort and interrupting usual activities.

§This is not the only side effect that caused women to stop taking ORILISSA.

¶2090 women were treated with ORILISSA in the phase 2 and phase 3 studies.

¶Percentages based on 324 women with a history of depression and 217 women taking antidepressants in the clinical studies.

Please see Use and additional Important Safety Information on pages 14-15.

Please see accompanying Full Prescribing Information, including Medication Guide, and discuss with your doctor.



QUESTIONS ABOUT SAFETY CONSIDERATIONS? We've got answers.

Will ORILISSA affect my period?



With ORILISSA, you may have lighter, less frequent or irregular periods, or no periods at all. This can make it hard to know if you're pregnant. You shouldn't take ORILISSA if you are pregnant or trying to get pregnant, so watch for other signs of pregnancy such as breast tenderness, weight gain, and nausea.

What do I do if I become pregnant while taking ORILISSA?



Do not take ORILISSA if you are trying to become or are pregnant. If you think you are pregnant, stop taking ORILISSA right away and call your doctor. If you become pregnant while taking ORILISSA, you are encouraged to enroll in the Pregnancy Registry in order to collect information about the health of you and your baby. Talk to your doctor or call 1-833-782-7241 to enroll.

Can I breastfeed while taking ORILISSA?



If you're breastfeeding or plan on breastfeeding while taking ORILISSA, talk to your doctor. The impact of ORILISSA on breast milk and the nursing baby is not known, so ask your doctor about the best way to feed your baby while on ORILISSA.

Why is it important to use effective birth control with ORILISSA?



ORILISSA does not prevent pregnancy. You'll need to use effective methods of birth control while taking ORILISSA and for one week after you stop taking it. Birth control pills that contain estrogen may make ORILISSA less effective. It's not known how well ORILISSA will

(Continued on next page)

work while you're taking progestin-only birth control. So, talk to your doctor about which birth control to use. They may change your birth control before you start taking ORILISSA.

What's bone mineral density (BMD)?



To understand BMD, or bone mineral density, first let's chat about bone. Bone's a living tissue. Throughout one's life, estrogen helps the body break down old bone to replace it with new bone. When estrogen levels are lower, the body may break down old bone faster than it replaces it—causing bone loss (or decreased BMD). This can happen anytime estrogen levels are lower—while breastfeeding, throughout pregnancy, during endurance exercise, or if you're taking medications that lower estrogen.

How can ORILISSA affect my BMD?

Since ORILISSA works by lowering estrogen, it can cause BMD loss. And after stopping ORILISSA, BMD may improve, but complete recovery may not occur. It's also not known if these bone changes could increase the risk for broken bones as you age.

What can I do about BMD?

Start by talking to your doctor. They may advise you to take vitamin D and calcium supplements as part of a healthy lifestyle that promotes bone health. They may also order a DXA scan (a type of X-ray) to check your BMD. Lastly, don't forget to tell your doctor if you have or have had broken bones and if you have other conditions or take medicine that may cause bone problems.

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Orilissa[®] COMPLETE

Orilissa Complete, the resources you need when you need them.

Starting a new medication can prompt a lot of questions, so give us a call. We're here to help whenever you may need us. We'll help you stay on track with your prescribed treatment plan and give you personalized support. For medical advice, remember to always talk to your doctor.

Once enrolled in Orilissa Complete, you have access to:

- SAVINGS
- HELP UNDERSTANDING YOUR CONDITION
- HELP UNDERSTANDING INSURANCE

Two easy ways to join Orilissa Complete:



Visit ORILISSA.com/Sign-Up



Call us at 1-800-ORILISSA

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GET PERSONALIZED SUPPORT

Orilissa Complete, here's what you need to know:



You may be able to save on the cost of your prescription with the Orilissa Complete Savings Card.*



Regardless of your insurance coverage, you'll have access to an Orilissa Complete Insurance Specialist to help you understand your coverage and identify possible ways to save† on your prescription.



After enrolling, you may receive a call from Orilissa Complete within the next 3 business days if additional insurance information is needed.

Give us a ring!

Orilissa Complete is here to support you, so don't hesitate to reach out. If you have any questions, call us at 1-800-ORILISSA (1-800-674-5477).

Live support hours:

We're available Monday through Friday, 9 AM-9 PM ET.

*Eligibility requirements apply.

†For eligible, commercially insured patients. Terms and Conditions apply.

Please see Use and Important Safety Information on pages 14-15.

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SAVE ON ORILISSA



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

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 Full Prescribing Information, including Medication Guide, and discuss with your doctor.



What's a savings card?



IMAGINE THE ORILISSA SAVINGS CARD AS A COUPON.



IT CAN HELP LOWER YOUR OUT-OF-POCKET COST FOR YOUR MONTHLY PRESCRIPTION.



WHEN PAYING FOR YOUR MEDICATION AT THE PHARMACY, HAND THE CARD DIRECTLY TO YOUR PHARMACIST.



RECEIVE ORILISSA THROUGH MAIL ORDER? CALL THEM DIRECTLY TO GIVE YOUR SAVINGS CARD INFO.



USE AND IMPORTANT SAFETY INFORMATION ABOUT ORILISSA

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 under 18 years of age.

IMPORTANT SAFETY INFORMATION

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

ORILISSA may cause serious side effects, including bone loss and effects on pregnancy:

• Bone Loss (decreased Bone Mineral Density [BMD])

While you are taking ORILISSA, your estrogen levels will be low. This can lead to BMD loss. 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. Your healthcare provider (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 one week 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 or may be pregnant, have osteoporosis, have severe liver disease, or take medicines known as strong OATP1B1 inhibitors, such as cyclosporine or gemfibrozil. If you are unsure if you are taking one of these medicines, ask your HCP.

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, have other conditions, or take medicines 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 pills. Your HCP may advise you to change the pills you take or 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 right away, or call 911 if an emergency, if you have any of these symptoms, especially if they are new, worse, or bother you: thoughts about suicide or dying, try 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 or 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 doctor or 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 HCP 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.

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