

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

ORILISSA®

elagolix (as elagolix sodium) tablets

Read this carefully before you start taking ORILISSA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ORILISSA.

What is ORILISSA used for?

- ORILISSA is used to treat the painful symptoms of endometriosis.
- Endometriosis happens when the tissue that forms the lining of the womb grows in other parts of the body. This can cause pain when you have your period, during other times of the month or during sex.
- It is not known if ORILISSA is safe and effective in children under 18 years old.

How does ORILISSA work?

Estrogen is the hormone that causes the tissues lining your womb to thicken each month. When estrogen levels go down, the tissues break down and you get your period. When this happens to tissues growing outside of your womb, you can bleed inside your body. This causes pain and scars to form. ORILISSA treats endometriosis by lowering the amount of estrogen in your body. The symptoms of endometriosis often get better after 1 month of taking ORILISSA.

ORILISSA improves the symptoms of endometriosis, such as:

- pain during periods
- pain between periods
- heavy bleeding during periods
- pain during sex
- pain or discomfort in the belly or pelvic region

Patients who take ORILISSA are often able to stop taking other kinds of pain medications for endometriosis. Talk to your healthcare professional to see if this is an option for you.

ORILISSA may help you feel better by reducing your pain. It may also improve your emotional well-being, and help you feel like you have more control over your symptoms.

What are the ingredients in ORLISSA?

Medicinal ingredients: elagolix (as elagolix sodium)

Non-medicinal ingredients: magnesium stearate, mannitol, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium carbonate monohydrate, talc, and titanium dioxide.

The 150 mg tablet also contains carmine high tint.

The 200 mg tablet also contains iron oxide red.

ORLISSA comes in the following dosage forms:

- 150 mg elagolix (as elagolix sodium) tablets. The tablets are light pink, oval, and imprinted with “EL 150” on one side.
- 200 mg elagolix (as elagolix sodium) tablets. The tablets are light orange, oval, and imprinted with “EL 200” on one side.

Do not use ORLISSA if you:

- are allergic to elagolix or to any of the other ingredients in ORLISSA (see the section **What are the ingredients in ORLISSA?**)
- are pregnant or think you might be pregnant
- have severe liver disease
- know you have osteoporosis
- have unexplained bleeding from your vagina
- are taking cyclosporine, used to prevent organ rejection in people who have had organ transplants, or gemfibrozil, used to lower high cholesterol

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ORLISSA. Talk about any health conditions or problems you may have, including if you:

- have a history of bone mineral loss. ORLISSA may result in a small loss of minerals from bone. The bone mineral loss may be increased during treatment with ORLISSA if you:
 - use alcohol excessively
 - smoke
 - have a family history of osteoporosis (thinning of the bones with fractures)

- take other medications that can cause thinning of the bones, for example steroids
- have liver problems
- have a history of mental health problems such as depression or suicidal thoughts
- are pregnant or trying to get pregnant. You should not become pregnant while taking ORILISSA. ORILISSA may affect the way your unborn baby develops or cause early pregnancy loss (miscarriage). If you think you have become pregnant while taking ORILISSA, stop taking ORILISSA and contact your healthcare professional immediately.
- are breastfeeding or plan to breastfeed. The effects of ORILISSA on breast milk and the nursing baby are not known. Talk to your healthcare professional about the best way to feed your baby if you take ORILISSA.

Other warnings you should know about:

Birth control

ORILISSA is **NOT** birth control. ORILISSA does not prevent pregnancy. You will need to use effective methods of birth control while taking ORILISSA. Talk to your healthcare professional about which birth control to use while taking ORILISSA. Your healthcare professional may change your birth control when you start treatment with ORILISSA as hormonal birth control that contains estrogen can affect how ORILISSA works. You must continue to use effective birth control for one week after stopping treatment with ORILISSA.

Bleeding changes

ORILISSA may change your periods. This may lead to:

- irregular bleeding or spotting
- increase or decrease in bleeding
- no bleeding at all

These changes may make it harder to know if you are pregnant. Periods generally come back about 4 weeks after stopping ORILISSA.

Bone health

Taking ORILISSA can result in a small loss of minerals from your bones. If you use ORILISSA for a long time, it may increase the risk of weak, porous bones (osteoporosis). This could increase the risk of broken bones, especially after menopause. Your bones may not recover completely when you stop taking ORILISSA. While you are taking ORILISSA, your healthcare professional may tell you to:

- exercise regularly
- eat a healthy diet

- take vitamin D, calcium supplements

Your healthcare professional may order an X-ray test after 1 year of use of ORILISSA or more often, if needed. This test, called DXA, is used to check your bone health.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. The following medicines may interact with ORILISSA:

- digoxin, which is used to treat some heart conditions
- rifampin, which is used to treat certain infections
- midazolam, which is used to treat anxiety
- rosuvastatin, which is used to lower blood cholesterol
- hormonal birth control that contains estrogen, such as “the pill”

How to take ORILISSA:

Before you start taking ORILISSA, be sure you understand what it is and how to take it. Take ORILISSA as directed by your doctor. If you have questions about ORILISSA, ask your healthcare professional.

Take ORILISSA at about the same time each day, even if you don't have any symptom. You may take ORILISSA with or without food.

You should start taking ORILISSA during your period to ensure you are not pregnant. You must confirm that you are not pregnant before starting treatment with ORILISSA.

Usual adult dose:

Your healthcare professional may prescribe either:

- ORILISSA 150 mg (a light pink tablet) once a day
- ORILISSA 200 mg (a light orange tablet) twice a day

Overdose:

If you think you have taken too much ORILISSA, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

150 mg once a day: take it as soon as you remember, as long as it is on the same day. Do not take more than 1 tablet each day.

200 mg twice a day: take it as soon as you remember, as long as it is on the same day. Do not take more than 2 tablets each day.

What are possible side effects from using ORLISSA?

These are not all the possible side effects you may feel when taking ORLISSA. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- hot flash
- night sweats
- headache
- dizziness
- feeling sick to the stomach (nausea)
- diarrhea, stomach pain, constipation
- weight increase
- difficulty sleeping
- anxiety, depression, irritability
- mood swing
- decreased sex drive (libido)
- runny, stuffy nose, sore throat, sinus infection, common cold
- joint pain
- menstrual bleeding changes:
 - irregular bleeding or spotting
 - increase or decrease in bleeding
 - no bleeding at all

ORLISSA can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Mood Changes: feeling sad or depressed, being tearful, loss of interest in daily activities, thoughts of harming yourself (suicidal thoughts)		✓	
VERY RARE			
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>

Storage:

Store between 2 and 30°C.

Keep out of reach and sight of children.

If you want more information about ORILISSA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (www.canada.ca/en/health-canada), the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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