DOSING AND ADMINISTRATION GUIDE

THE ORILISSA DIFFERENCE—2 ORAL DOSAGES TO FIT HER NEEDS[1]

ORILISSA IS DIFFERENT THAN MANY OTHER TREATMENT OPTIONS FOR ENDOMETRIOSIS PAIN—FEATURES TO CONSIDER:

ORILISSA is the first FDA-approved pill specifically developed for **moderate to severe** endometriosis pain in over a decade. It is not a birth control pill, surgery, or an injection. It does not contain hormones

Two different doses of ORILISSA **dial down estradiol** to 2 different levels, allowing you to individually tailor treatment

DOSING SCHEDULE

- 1 monthly carton contains 4 weekly blister packs
- Take at approximately the same time each day
- In case of a missed dose, take as soon as remembered, as long as it is on the same day, then resume regular dosing schedule

ORILISSA 150 mg QD
NDC 0074-0038-28
Take AM or PM
No more than 1 tablet each day

ORILISSA 200 mg BID
NDC 0074-0039-56
Take AM and PM
No more than 2 tablets each day

Pills pictured are not actual size.

	ORILISSA 150 mg QD	ORILISSA 200 mg BID
Dysmenorrhea	✓	✓
Non-menstrual pelvic pain (NMPP)	✓	✓
Dyspareunia	Pain relief not statistically significant in trials	✓
Duration of use	Limited to **24 months**	Limited to **6 months**

LIMIT THE DURATION OF USE BASED ON THE DOSE AND COEXISTING CONDITION

- Use of **150 mg QD** is recommended for women with moderate hepatic impairment (Child-Pugh B) with the duration of treatment limited to **6 months**. Use of **200 mg BID** is **not recommended** for women with moderate hepatic impairment
  - No dosage adjustment of ORILISSA is required in women with mild hepatic impairment (Child-Pugh A)

IMPORTANT NEXT STEPS WHEN PRESCRIBING OR DISPENSING ORILISSA[1]

- Exclude pregnancy before starting ORILISSA, or start ORILISSA within 7 days from the onset of menses
- Advise patients to take ORILISSA orally at approximately the same time each day, with or without food
- Use the lowest effective dose based on severity of symptoms and treatment objectives
- Limit the duration of use because of bone loss

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.

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

Orilissa®
elagolix tablets 150 mg 200 mg

IMPORTANT SAFETY INFORMATION (cont'd)

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 additional Important Safety Information on previous page and full Prescribing Information at http://www.rxabbvie.com/pdf/orilissa_pi.pdf.

Find out more at ORILISSA.com/hcp

Reference: 1. Orilissa [package insert]. North Chicago, IL: AbbVie Inc.

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Orilissa®
elagolix tablets 150 mg 200 mg