Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/helping-patients-manage-moderate-to-severe-endo-pain-with-an-oral-therapy-option/11700/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Helping Patients Manage Moderate to Severe Endo Pain With an Oral Therapy Option

Hi. I'm Dr. Chuck Miller. I'm the Director of Minimally Invasive Gynecologic Surgery at Advocate Lutheran General Hospital in Park Ridge, Illinois. My practice mainly focuses on the treatment of infertile couples and the performance of minimally invasive gynecologic surgery. I have a special interest in the treatment of endometriosis.

Endometriosis pain and the role of ORILISSA

As we know, endometriosis is a chronic, progressive disease with debilitating pain. It is essential, as a healthcare professional, that one diagnoses early, treats effectively, and that we plan for long-term management because the symptoms can have a significant negative effect on the day-to-day activities of women's lives. They can affect women at home with their families, at their jobs, and at their school. One option to consider is ORILISSA. I recommend ORILISSA to my peers based on my own personal success that I've had with my patients. ORILISSA was rigorously studied. This treatment has a well-characterized safety profile. We know how Orilissa works. ORILISSA works for the three most common types of endometriosis pain: dysmenorrhea,[1,2] non-menstrual pelvic pain,[1,2] and dyspareunia.[1,2*] ORILISSA was FDA approved at a 150-mg dosage once daily for two years, and a 200-mg twice daily dosage for six months.

How ORILISSA is different and how it works

ORILISSA's different. It is the first FDA approved pill specifically developed for moderate to severe endometriosis pain in over a decade. It's not a birth control pill, surgery, or an injection. It does not contain hormones. ORILISSA comes in two different doses that dial down estradiol to two different levels. This lets us individually tailor treatment based on each patient's needs. I always utilize the lowest effective dose whenever possible. If a patient's main concern, however, is painful intercourse, I may utilize the 200-mg twice daily dose. One feature of ORILISSA is that it starts and stops working rapidly. Suppression of estradiol levels occur within approximately 24 hours[3,4†] and estrogen levels return to baseline 24-48 hours after patients stop taking the drug.[3,4] After six months of therapy with ORILISSA, the majority of women reported resumption of menses within one month of stopping treatment.

Prescribing ORILISSA in practice

I have prescribed ORILISSA to a number of my appropriate patients and so have more than 10,000 healthcare providers nationwide. One patient that comes to mind is a young woman who came to me as a referral for surgery. Her primary complaint was persistent non-menstrual pelvic pain, despite the oral contraceptive that she was taking. Before treatment with ORILISSA, her endometriosis pain was affecting her life, as she reported having been prescribed analgesics, days of missed work, due to her pain. While surgery certainly may be a viable option for some patients, together, after discussion, we chose to start her on ORILISSA 150 mg once daily. Now, you could say she is doing well, and her pain is reduced. The difference is noticeable. And let's face it, so many of our patients are pushing through their pain at work. ORILISSA is oftentimes an option for them as well. At the end of the day, ORILISSA is an effective drug for the treatment of moderate to severe pain symptoms related to endometriosis. I've adopted ORILISSA and begun recommending it regularly as a potential therapy to any patient who presents to me with moderate to severe pain related to endometriosis that has failed first tier treatment and does not have an obvious reason to go to surgery.

INDICATION

ORILISSA® (elagolix) is indicated for the management of moderate to severe pain associated with endometriosis.

IMPORTANT SAFETY INFORMATION

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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, or with concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil).

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. Consider assessment of BMD in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss, and do not use in women with known osteoporosis.
- 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.

Reduced Efficacy with Estrogen-Containing Contraceptives

- Based on the mechanism of action of ORILISSA, estrogen-containing contraceptives are expected to reduce the efficacy of ORILISSA. The effect of progestin-only contraceptives on the efficacy of ORILISSA is unknown.
- Advise women to use non-hormonal contraceptives during treatment and for one week after discontinuing ORILISSA.

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 patients less than 18 years of age have not been established.
For more information, see accompanying full prescribing information.

References:

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1. Orilissa (package insert). North Chicago, IL: AbbVie Inc. **2.** Fuldeore MJ, Soliman AM. Prevalence and symptomatic burden of diagnosed endometriosis in the United States: national estimates from a cross-sectional survey of 59,411 women. *Gynecol Obstet Invest*. 2017;82(5):453-461. **3.** Ng J, Chwalisz K, Carter DC, Klein CE. Dose-dependent suppression of gonadotropins and ovarian hormones by elagolix in healthy premenopausal women. *J Clin Endocrinol Metab*. 2017;102(5):1683-1691. **4.** Struthers RS, Nicholls AG, Grundy J, et al. Suppression of gonadotropins and estradiol in premenopausal women by oral administration of the nonpeptide gonadotropin-releasing hormone antagonist elagolix. *J Clin Endocrinol Metab*. 2009;94(2):545-551.

*Statistical significance for dyspareunia was not achieved with 150 mg QD dose of ORILISSA.[1]
†Does not imply onset of efficacy at this time.

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