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Clinical Resource center

The Potential Role of Elagolix for Treating Uterine Bleeding Associated to Uterine Myomas

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Uterine Myomas are widespread gynecological condition affecting up to 80% of women by age 50. Heavy Menstrual Bleeding (HMB) driven by uterine myomas is a common clinical challenge, often leading to anemia and significantly reduced quality of life. Effectively managing this symptom medically, especially for women seeking to avoid or delay surgery, remains a key focus in gynecologic care.

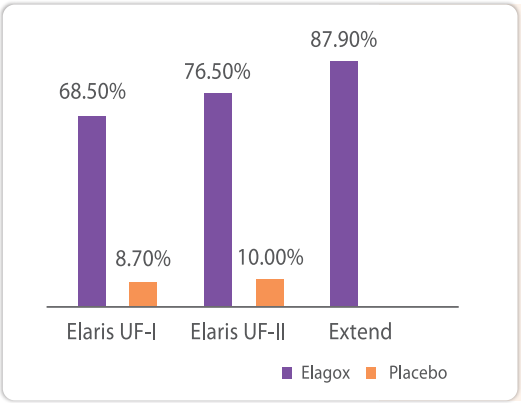
The Solution: Elagolix - A Novel Oral GnRH Antagonist

Orally active, non-peptide antagonist that reversibly blocks the GnRH receptor in the pituitary.

Rapid, dose-dependent suppression of LH, FSH, & consequently, ovarian estrogen & progesterone production.

- Avoids the initial "flare-up" effect
- Provides immediate suppression
- Quick reversibility upon discontinuation

Promising Efficacy Data from Clinical Trials



- **Phase II:** Established that elagolix significantly reduces menstrual blood loss (MBL) in a dose-dependent manner. The 300 mg twice daily (BID) dose was identified as optimal, showing the highest efficacy in reducing MBL and fibroid volume.
- **Pivotal Phase III (ELARIS UF-I & UF-II):** These large, placebo-controlled trials confirmed the high efficacy (69-77% response) of Elagolix vs. placebo (<10%) over 6 months.
- **Long-Term Extension (ELARIS UF-EXTEND):** Demonstrated the sustainability of elagolix + add-back therapy for up to 12 months of total treatment. It showed maintained efficacy with an 87.9% response rate.

Conclusions

Elagolix represents a safe and highly effective oral option for the medical management of HMB in women with uterine myomas. It successfully reduces blood loss, improves anemia and quality of life, with a manageable safety profile.

Ref.: Barra F, Vitale SG, Seca M, et al. The potential role of elagolix for treating uterine bleeding associated to uterine myomas. Expert Opin Pharmacother. 2020;21(12):1419-1430. doi:10.1080/14656566.2020.1755254

Elagolix: An Oral GnRH Antagonist for Endometriosis pain

Elagox®

Elagolix 150, 200 mg Tablet

Drug Review

Introduction[1]

Endometriosis affects about 1 in 10 women of reproductive age and remains one of the leading gynecologic causes of hospitalization. Its chronic, inflammatory nature results in dysmenorrhea, non-menstrual pelvic pain, and dyspareunia, which are the most distressing symptoms and contribute substantially to impaired daily functioning. Pain severity often does not correlate with disease stage, making management particularly challenging.

Gaps in current treatment options

- Analgesics such as NSAIDs are commonly used to alleviate pain, but high-quality evidence for meaningful benefit is limited, and no single NSAID is preferred.[2]
- Surgical options (e.g., laparoscopy) can relieve symptoms for some, yet evidence for durable pain relief is of low to moderate quality and recurrence is not uncommon.[3]
- Hormonal therapies (e.g., GnRH agonists) are effective but often limited by hypoestrogenic adverse effects (hot flashes, bone loss) and treatment duration caps.[4]
- Older GnRH antagonists are synthetic peptides require subcutaneous injections, implantation of long-acting depots. The peptide structure is responsible for histamine-related adverse events & the tendency to elicit hypersensitivity reactions.[4]

Elagolix: Breakthrough treatment for moderate to severe endometriosis pain[1]

- Elagolix is an oral, non-peptide GnRH receptor antagonist that competitively blocks pituitary GnRH receptors, lowering LH/FSH and thereby reducing estradiol & progesterone to relieve endometriosis pain.

Elagolix competitively & reversibly binds with GnRH receptor → Blocks the binding of endogenous GnRH to the receptor → Inhibits pituitary Gonadotropin (FSH,LH) release → Inhibits estrogen and progesteone release from ovary → **Decreases endometriosis pain**

- Its rapid onset (Tmax ≈ 1 h) and short half-life (4–6 h) allow faster reversibility than GnRH agonists.
- Quick and reversible dose-dependent suppression: 150 mg QD maintains low estradiol, while 200 mg BID produces near-complete suppression-enabling titration to balance efficacy and hypoestrogenic effects.

Clinical efficacy

- In two Phase 3 trials (ELARIS EM-1/EM-2), elagolix significantly improved dysmenorrhea response rates vs placebo (e.g., 46.4% [150 mg QD] and 75.8% [200 mg BID] vs 19.6% placebo in EM-1) and improved non-menstrual pelvic pain at both doses vs placebo.[5]
- Elagolix 200 mg BID dose showed statistically significant benefit for dyspareunia.[6]
- Long-term extensions (EM-3/EM-4) showed maintained responses through 12 months (dysmenorrhea ~51–78% responders; non-menstrual pelvic pain ~66–69%; dyspareunia ~46–60% depending on dose/study).[5]
- Elagolix is well tolerated, with less pronounced hypoestrogenic effects compared with GnRH agonists.[5]

Ref.: 1. Urits, Ivan et al. "An Evidence-Based Review of Elagolix for the Treatment of Pain Secondary to Endometriosis." Psychopharmacology bulletin vol. 50,4 Suppl 1 (2020): 197-215.; 2. Brown J, et al. NSAIDs for pain in women with endometriosis (Cochrane). 2017.; 3. Duffy JMN, Arambage K, Correa FJS, Olive D, Farquhar C, Garry R, Barlow DH, Jacobson TZ.Laparoscopic surgery for endometriosis. Cochrane Database of Systematic Reviews. 2014.; 4. Ng J, Chwalisz K, Carter DC, Klein CE. Dose-dependent suppression of gonadotropins and ovarian hor-mones by elagolix in healthy premenopausal women. J Clin Endocrinol Metab. 2017;102(5):1683–1691.; 5. Agarwal, Sanjay K et al. "Endometriosis-Related Pain Reduction During Bleeding and Nonbleeding Days in Women Treated with Elagolix." Journal of pain research vol. 14 263-271. 2 Feb. 2021, doi:10.2147/JPR.S284703.; 6. Taylor HS, Giudice LC, Lessey BA, Abrao MS, Kotarski J, Archer DF, Diamond MP, Surrey E,Johnson NP, Watts NB, Gallagher JC, Simon JA, Carr B, Dmowski WP, Leyland N, Rowan JP,Duan WR, ... Chwalisz K. Treatment of endometriosis-associated pain with elagolix, an oral GnRHantagonist. N Engl J Med. 2017

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Full prescribing information is available upon request