

RELIEVE Pain, RESTOR E Balance





Elagolix 150 mg / 200 mg Tablets

ENDOMETRIOSIS- INTRODUCTION:

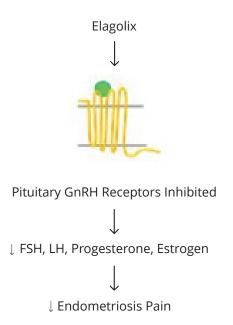
- Endometriosis is a painful condition where tissue similar to the lining of the uterus grows outside of the uterus.
- Endometriosis is found in 45% 82% of women with chronic pelvic pain and in 2.1%-78% of infertile women.

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MECHANISM OF ACTION:

- Elagolix is an orally administered, nonpeptide small molecule GnRH antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland.
- Administration of Elagolix results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones, estradiol and progesterone.
- In women, inhibition of FSH and LH prevents the production of estrogen by the ovaries. Inhibition of GnRH signalling may treat or prevent symptoms of sex hormone-dependent disease states.



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<u>CLINICAL STUDY</u>:

AIM:

To evaluate the effects of two doses of elagolix — 150 mg once daily (lower-dose group) and 200 mg twice daily (higher-dose group) — as compared with placebo in women with endometriosis associated pain.

STUDY TYPE:

NO. OF PATIENTS:

STUDY DURATION:

Double-blind, Randomized.

150 mg once daily and 200 mg twice daily.

872 women underwent randomization in Elaris EM-I and 817 in Elaris EM-II.

DOSE:

6 months.

RESULTS:

As compared with placebo, each elagolix dose resulted in a significant reduction from baseline to 3 months in endometriosis-associated pain and significant reductions from baseline to 6 months in scores with respect to dysmenorrhea and nonmenstrual pelvic pain.

Study group	Outcome	% of Women (Lower-Dose Elagolix)	% of Women (Higher-Dose Elagolix)	Placebo (%)
Elaris EM-I	Dysmenorrhea	46.4%	75.8%	19.6%
	Nonmenstrual Pelvic Pain	50.4%	54.5%	36.5%
Elaris EM-II	Dysmenorrhea	43.4%	72.4%	22.7%
	Nonmenstrual Pelvic Pain	49.8%	57.8%	36.5%

Table : Reduction in Dysmenorrhea and Nonmenstrual Pelvic Pain.

CONCLUSION:

Both higher and lower doses of elagolix were effective in improving dysmenorrhea and nonmenstrual pelvic pain during a 6-month period in women with endometriosis-associated pain.

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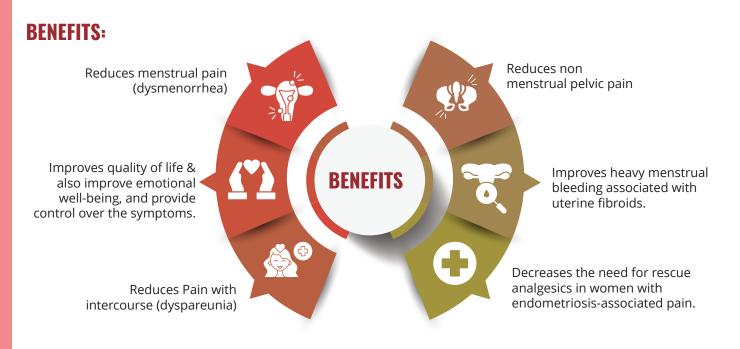
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DESCRIPTION:

Elagolix is an oral, short-acting, nonpeptide, gonadotropin-releasing hormone (GnRH) receptor antagonist that suppresses ovarian estrogen production in a dose-dependent manner.

INDICATION:

Endometriosis associated pelvic pain (Moderate to Severe).



DOSAGE AND ADMINISTRATION:

150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months.

REFERENCES:

1) N Engl J Med 2017;377:28-40 2) J Clin Diagn Res. 2015 Jun 1;9(6):QC01–QC03. 3) Menopause. 2020 Feb;27(2):238–242. 4) Clin Pharmacokinet. 2019 Nov 21;59(3):297–309. 5) ACOG.ORG



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