

US FDA approves ORILISSA(Elagolix Sodium) first ever drug with an indication for management of moderate to severe pain associated with Endometriosis approved on 23th July 2018



AbbVie Receives U.S. FDA Approval of ORILISSA™ (elagolix) for the Management of Moderate to Severe Pain Associated with Endometriosis



Endometriosis

The hormonal condition that causes painful periods, chronic pelvis pain, pain during sex and infertility

Endometriosis Burden

What is Endometriosis?

A disorder in which tissue that normally lines the uterus grows outside the uterus.

Common Symptoms of Endometriosis:

- Very painful menstrual cramps
- Very heavy menstrual bleeding
- Heavy spotting or bleeding between periods
- Inability or difficulty in becoming pregnant

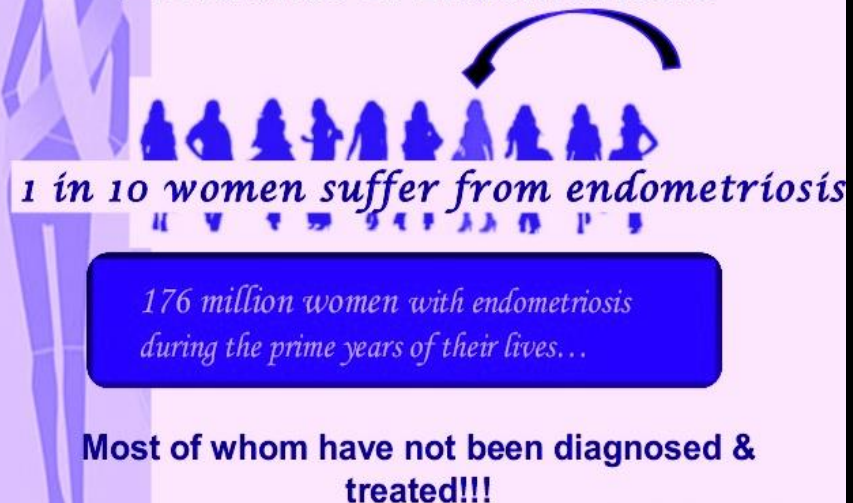
Signs of Endometriosis:

- Rapid or irregular heartbeat
- Fluctuating blood pressure
- Slightly elevated or reduced body temperature
- Abnormal blood levels of reproductive hormones

Facts and Figures

Prevalence estimates suggest that **endometriosis** affects as many as 10% of premenopausal women **worldwide**,^{1, 2} and approximately 30–50% of symptomatic women,⁷ but these studies are typically limited by the selection of high-risk patients.

Prevalence of Endometriosis



Endometriosis Around the World

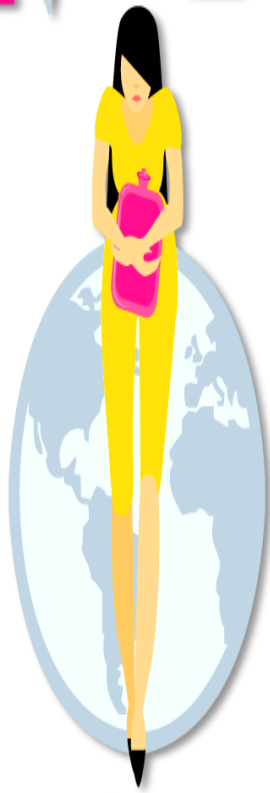
Endometriosis is NOT rare⁶
It is the 2nd
most common
gynaecological
condition in the UK

On average it takes³
7.5 years
to get a
diagnosis
in the UK

1 in
10
women of reproductive age in the
UK suffer from endometriosis¹



ENDOMETRIOSIS
costs the UK
ECONOMY **£8.2 bn**²
In treatments, loss of work & healthcare costs per year



ONLY 1/3
of women feel
their **current**
pain treatment is effective

Currently, there is
NO
DEFINITE CURE FOR
endometriosis

40%
of infertile women are
affected by endometriosis

176 million women
worldwide are affected by
endometriosis¹

10 years
is the average time
it takes for a woman
to be **DIAGNOSED**
with endometriosis

82%
of women are at
times unable to
carry out **DAY-TO-
DAY** activities due
to
endometriosis

30% to 50%
of women with
endometriosis may
experience
INFERTILITY

1 in 10
women

get affected by
endometriosis
during their
REPRODUCTIVE
years (ages of 15 to
49)

176
million

women in
the world
have
ENDOMETRIOSIS

27

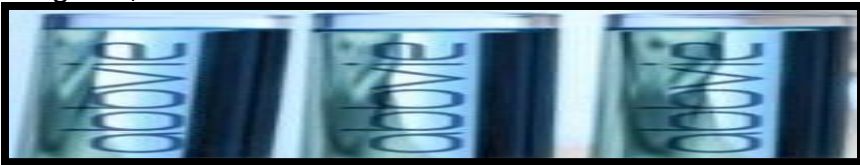
is the **AVERAGE**
age when a
woman is first
diagnosed
with
endometriosis

68%
of women with
endometriosis were
initially **MISDIAGNOSED**
with another
condition

About ORILISSA (Elagolix Sodium) (1)

About the AbbVie

- AbbVie is a publicly traded biopharmaceutical company in cooperation with Neurocrine Biosciences, Inc. founded in 2013. It originated as a spin-off of Abbott Laboratories.
- Neurocrine Biosciences, a San Diego based biopharmaceutical company, is focused on developing treatments for neurological and endocrine related disorders.
- Marketed under the brand name Orilissa, the medicine should be available in pharmacies at the beginning of August,.
- Elagolix was named one of the top 10 prospective drug launches of the year by the analytical firm Evaluate in its 2018 preview, with projected annual sales of \$934 million by 2022.
- Analysts on average estimate AbbVie drug could generate \$40 million in sales by the end of the year. In 2019, that estimate climbs to \$277 million, and for 2020, analysts project sales around \$576 million. In the year following, estimates climb to as high as \$1.23 billion.



Brief on Orilissa (Elogolix Sodium)

ORILISSA (Elagolix Sodium) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

DOSAGE FORMS AND STRENGTHS: Oral tablets: 150 mg and 200 mg



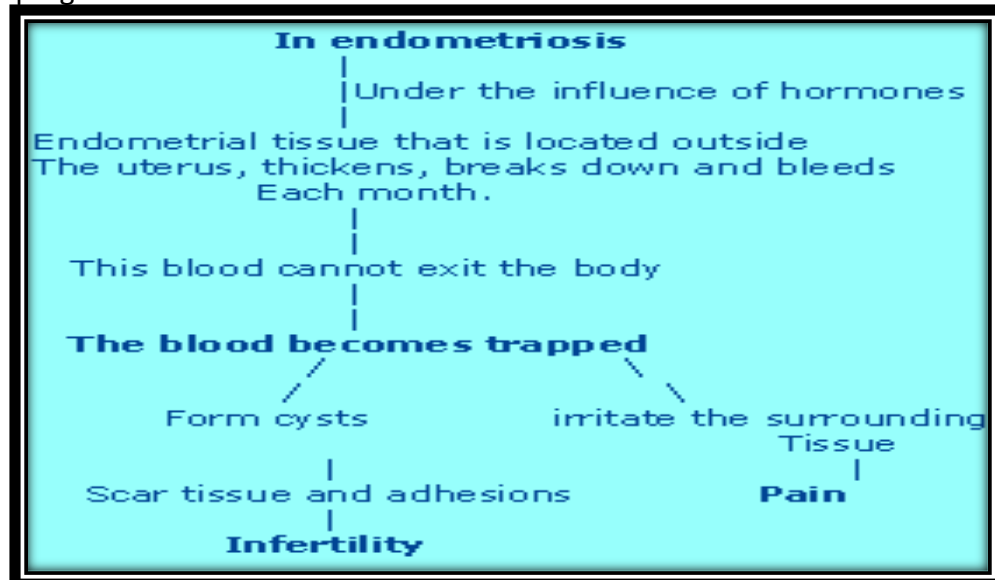
About ORILISSA (Elagolix Sodium) (2)

Product information

- **DOSAGE AND ADMINISTRATION:**
 - **Normal liver function or mild hepatic impairment:** 150 mg once daily for up to 24 months or 200 mg twice daily for up to 6 months.
 - **Moderate hepatic impairment:** 150 mg once daily for up to 6 months.
- **CONTRAINDICATIONS:** Pregnancy, Known osteoporosis, Severe hepatic impairment, Strong organic anion transporting polypeptide (OATP) 1B1.
- **ADVERSE REACTIONS:** 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.
- **WARNINGS AND PRECAUTIONS:** Bone loss; Reduced Ability to Recognize Pregnancy; Suicidal Ideation and Mood Disorders; Hepatic Transaminase Elevations; Potential for Reduced Efficacy with Estrogen-Containing Contraceptives.

Mechanism of action

ORILISSA is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of ORILISSA 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.



Market Overview - Endometriosis

Current Treatment options

- **Pain medication:** NSAIDs.
- **Hormone therapy.**
- Therapies used to treat endometriosis include:
 - Hormonal contraceptives:** Birth control pills, patches and vaginal rings.
 - Gonadotropin-releasing hormone (Gn -RH) agonists and antagonists.**
 - Progestin therapy:** An intra- uterine device (Mirena), contraceptive implant, contraceptive injection (Depo-Provera) or progestin pills,
 - Aromatase inhibitors.**
- **Conservative surgery**
- **Fertility treatment**
- **Hysterectomy with removal of the ovaries**

Top Competitive Landscape for Orilissa

Myovant's drug, relugolix, works by suppressing estrogen to low levels, and then reintroducing just enough so that it doesn't lead to bone density loss.

Allergan is developing Esmya, a Drug that is being investigated for use in uterine fibroids.

Bayer's drug, vilaprisan, also works by modulating progesterone levels to treat uterine fibroids and endometriosis.



Source: <https://www.mayoclinic.org/diseases-conditions/endometriosis/diagnosis-treatment/drc-20354661>

<https://www.businessinsider.in/A-new-treatment-for-a-condition-that-can-feel-like-tiny-people-skating-on-razor-blades-in-your-stomach-and-affects-an-estimated-200-million-women-just-got-approved/articleshow/65120770.cms>

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