Kyleena

(levonorgestrel)

New Product Slideshow

MPR

Introduction

- **Brand name:** Kyleena
- **Generic name:** Levonorgestrel
- **Pharmacological class:** Progestin IUD
- **Strength and Formulation:** Levonorgestrel 19.5mg; intrauterine system
- **Manufacturer:** Bayer Healthcare
- **How supplied:** System—1
- **Legal Classification:** Rx

KYLEENA


NDC 50419-424-01
1 Sterile Unit
Rx only
Kyleena™
(levonorgestrel-releasing intrauterine system)
19.5mg
IMPORTANT: To be inserted in the uterus by a trained healthcare provider. Kyleena cannot be reloaded. See physician insert for detailed instructions for use.
www.kyleena-us.com
BAYER

Indications

- Prevention of pregnancy for up to 5 years

Dosage & Administration

- See full labeling
- Insert into uterine cavity as directed
- Reexamine and evaluate 4–6 weeks after insertion; then yearly or more if needed
- Remove or replace after 5 years

Considerations for Special Populations

- **Pregnancy:** See Contraindications
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** Pre-menarche: not recommended
- **Elderly:** Women aged >65 years: not indicated

Contraindications

- Pregnancy
- Post-coital contraception
- Congenital or acquired uterine anomaly including fibroids
- Acute or history of pelvic inflammatory disease (PID) unless there has been a subsequent intrauterine pregnancy
- Postpartum endometritis or infected abortion in past 3 months
- Uterine or cervical neoplasia

Contraindications

- Breast or other progestin-sensitive cancer
- Uterine bleeding of unknown etiology
- Untreated acute cervicitis or vaginitis
- Active liver disease or tumor
- Conditions associated with increased susceptibility to pelvic infections
- Retained IUD

Warnings/Precautions

- Evaluate for ectopic pregnancy
- Risk of spontaneous abortion, miscarriage, sepsis, premature labor or delivery, congenital anomalies: **remove if pregnant**
- Consider risks of PID before using
- Remove if **endometritis** or **PID** recurs or if acute pelvic infection is severe or unresponsive to treatment

Warnings/Precautions

- **Bleeding pattern alterations:** exclude endometrial pathology prior to insertion in women with persistent or uncharacteristic bleeding
- Risk of perforation, expulsion, and ovarian cysts
- Increased risk of perforation in **lactating women** and women with fixed retroverted or not completely involuted uteri or during postpartum period; delay insertion a minimum of 6 weeks, until involution is complete after delivery or second trimester abortion

Warnings/Precautions

- **Consider removal** if coagulopathy, migraine, transient cerebral ischemia, severe headache, marked increase in BP, severe arterial disease, uterine/cervical malignancy, jaundice, or symptomatic actinomycosis occurs
- May be scanned with **MRI** under specific conditions

Interactions

- Caution with **anticoagulants**; consider removal
- May be **antagonized** by CYP3A4 inducers
- May be **potentiated** by CYP3A4 inhibitors

Adverse Reactions

- Vulvovaginitis
- Ovarian cyst
- Abdominal/pelvic pain
- Headache/migraine
- Acne/seborrhea
- Dysmenorrhea/ uterine spasm
- Breast pain/breast discomfort
- Increased bleeding
- Ectopic pregnancy
- Intrauterine pregnancy
- Sepsis
- PID
- Perforation
- Expulsion

Mechanism of Action

- Exact mechanism of continuously released levonorgestrel in contraceptive efficacy has not been conclusively demonstrated
- Studies have suggested several mechanisms that prevent pregnancy: thickening of cervical mucus to prevent passage of sperm into the uterus, inhibition of sperm capacitation or survival, and alteration of the endometrium

Clinical Trial

- Kyleena was evaluated in a randomized, open-label, multi-center trial (n=1,452) for the efficacy in preventing pregnancy for 5 years
- Excluded women included: <6 weeks postpartum with a history of ectopic pregnancy, clinically significant ovarian cysts, or HIV or those at high risk for sexually transmitted infections

Clinical Trial

- Primary efficacy endpoint was pregnancy rate, calculated as the Pearl Index (PI) in women aged 18–35 years
- PI based on 28-day equivalent exposure cycles
- Evaluable cycles excluded those in which back-up contraception was used unless pregnancy occurred in that cycle

Clinical Trial

- Year 1 PI was based on 2 pregnancies and the cumulative 5-year pregnancy rate was based on 13 pregnancies that occurred after treatment onset and within 7 days of Kyleena removal/expulsion
- There was a total of 57,313 evaluable 28-day cycles of exposure over 5 years
- The cumulative 5-Year Kaplan Meier rate was **1.45** (95% CI: 0.82, 2.53)
- For more clinical trial data, see full labeling

Kyleena Monograph

- For more information view the product monograph available at:

  http://www.empr.com/kyleena/drug/34634/