**INDICATION**

LILETTA® is a sterile, levonorgestrel-releasing intrauterine system indicated for prevention of pregnancy for up to 3 years. The system should be replaced after 3 years if continued use is desired.

**IMPORTANT SAFETY INFORMATION**

**Who is not appropriate for LILETTA**

Use of LILETTA is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUS; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of LILETTA.

Please see Important Safety Information throughout and accompanying full Prescribing Information.
Clinical considerations for use and removal of LILETTA
Use LILETTA with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. Because irregular bleeding/spotting is common during the first months of LILETTA use, exclude endometrial pathology (polyps or cancer) prior to the insertion of LILETTA in women with persistent or uncharacteristic bleeding. If the threads are not visible or are significantly shortened, they may have broken or retracted into the cervical canal or uterus. If LILETTA is displaced (eg, expelled or perforated the uterus), remove it.

Pregnancy related risks with LILETTA
If pregnancy should occur with LILETTA in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with LILETTA. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Educate her about PID
Insertion of LILETTA is contraindicated in the presence of known or suspected PID or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. About 1/3 of women diagnosed with PID developed the infection within a week of LILETTA insertion, while the remainder were diagnosed more than six months after insertion. Counsel women who receive LILETTA to notify a healthcare provider if they have complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, or genital lesions or sores. PID is often associated with sexually transmitted infections (STIs); LILETTA does not protect against STIs, including HIV. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death.

Expect changes in bleeding patterns with LILETTA
Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease.
Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

**Be aware of other serious complications and most common adverse reactions**

Some serious complications with IUSs like LILETTA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other LNG-releasing IUSs. Aseptic technique during insertion of LILETTA is essential in order to minimize serious infections such as GAS.

Perforation (total or partial, including penetration/embedment of LILETTA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy. If perforation occurs, locate and remove LILETTA. Surgery may be required. Delayed detection or removal of LILETTA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation is higher if inserted in lactating women and may be higher if inserted in women who are postpartum or when the uterus is fixed retroverted. Partial or complete expulsion of LILETTA may occur, resulting in the loss of contraceptive protection. Delay LILETTA insertion a minimum of 6 weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled LILETTA. If expulsion has occurred, a new LILETTA may be inserted within 7 days after the onset of a menstrual period after pregnancy has been ruled out. Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.
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Visit LILETTAAccessConnect.com or call 1-855-LILETTA (1.855.545.3882) and speak to a live representative

IMPORTANT SAFETY INFORMATION (continued)

Be aware of other serious complications and most common adverse reactions (continued)
In the clinical trial of LILETTA the most common adverse reactions (≥5% users) were vaginal infections (13.6%), vulvovaginal infections (13.3%), acne (12.3%), headache or migraine (9.8%), nausea or vomiting (7.9%), dyspareunia (7.0%), abdominal pain or discomfort (6.8%), breast tenderness or pain (6.7%), pelvic discomfort or pain (6.1%), depression or depressed mood (5.4%), and mood changes (5.2%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions.
Evaluate patients 4 to 6 weeks after insertion of LILETTA and then yearly or more often if clinically indicated.

Please see Important Safety Information throughout and accompanying full Prescribing Information.