Levonorgestrel Intrauterine System (LNG IUS)
Provider Information Sheet

PRODUCT DESCRIPTION

The levonorgestrel intrauterine system (LNG-IUS) consists of a plain plastic T-shaped frame with a hormonal reservoir around the vertical stem. The steroid hormone reservoir consists of a cylinder, made of LNG and a polydimethylsiloxane mixture, containing 52mg of LNG. The reservoir forms a 'sleeve' around the vertical arm of the plastic body and is covered by polydimethylsiloxane, which regulates the intrauterine release of the LNG. Minute amounts of LNG (20 µg/day) are released from the cylinder at a constant rate into the uterine cavity.

ACTIVE INGREDIENT: LEVONORGESTREL

The progestin levonorgestrel is a chemical-derivative of 19-nortestosterone. The levonorgestrel in the LNG-IUS is mainly locally active at the level of the endometrium in the uterus, and the systematic serum concentration of the hormone is much lower than other hormonal methods (i.e. birth control pills). Table I displays a comparison of LNG-IUS plasma concentration level with that of other hormonal contraceptive methods.

Because the LNG is released directly into the uterus, it is quickly absorbed through the endometrium. LNG can be detected in the plasma 15 minutes after insertion and the maximum plasma levels are reached within a few hours. A few weeks after insertion, plasma LNG concentrations reach a plateau of 150-200pg/mL, which is lower than those seen in, LNG implant, combined oral contraceptives and the mini-pill.

MECHANISM OF ACTION

The LNG-IUS contraceptive action works by primarily inhibiting fertilization, which is prevented by various local effects within the uterine cavity. Because it functions in this manner, LNG-IUS is not considered an abortifacient. With LNG-IUS, the uterine fluid is altered to contain a high amount of white blood cells and different cellular mediators that inhibit sperm motility in the uterine cavity. Secondly, the cervical mucus is thickened, blocking sperm from passing through the cervix into the uterus and oviduct (Fallopian tube), where fertilization may occur. Thirdly, LNG-IUS leads to the thinning and atrophy of the endometrial lining within 3 months of use, as the endometrial estrogen receptors are suppressed by LNG's effect in the uterus. This suppression is the reason why menstrual bleeding is reduced (and sometimes stopped) during LNG-IUS use.

LNG IUS METHOD ACCEPTORS

LNG-IUS may be appropriate for all women of reproductive age who need contraception, including women who **breastfeed;** there are no age or parity restrictions on its use. Today, LNG-IUS use among women who have not yet demonstrated their fertility, and use among women with multiple partners, is not contraindicated, yet use of other contraceptive methods should be encouraged. Other contraindications include pregnancy, pelvic inflammatory disease, gynecologic infections, cervical or uterine abnormalities and cancers, among others. The

patient must be properly assessed and properly counseled about these contraindications before LNG-IUS insertion.

INSERTION PROCEDURE

Proper LNG-IUS insertion is important for proper positioning within the uterus, lessening the risk of infection, perforation and expulsion, as well as ensuring uniform dispersion of LNG over the endometrium. The LNG-IUS should be inserted within 7 days from the onset of menstruation (because the low likelihood of pregnancy during this time).

- 6 weeks or longer (until full involution of the uterus) after childbirth
- Immediately after menstrual regulation or first trimester spontaneous or induced abortion, provided there is no infection

Acceptors of LNG-IUS must be screened and cleared of STIs, and it is the providers' responsibility to inspect the woman's reproductive tract, both externally and internally, for signs and symptoms of infection. LNG-IUS acceptors should be counseled before device insertion, and provided with an opportunity to ask questions and refuse insertion, if desired.

PATIENT COUNSELING

Thorough counseling improves user satisfaction and increases successful use of contraceptive method, including use of the LNG-IUS. Among the range of topics that should be covered in patient counseling, there are specific issues that should be emphasized with patients who are considering use of the LNG-IUS. These specifics include the following:

- LNG-IUS use does not protect from the transmission of HIV/AIDS
- There are side effects associated with insertion and use of LNG-IUS that should be detailed by provider and well-understood by the patient
- The LNG-IUS can be removed at any time; the patient's fertility will return shortly thereafter
- There are numerous additional health benefits to LNG-IUS use that should be listed and explained by the provider
- The placement of the LNG-IUS device can and should be checked regularly

EFFECTIVENESS

The **contraceptive effectiveness** of the LNG-IUS is fully comparable to that of female sterilization, but reversible. Initial studies of LNG-IUS effectiveness at preventing pregnancy included 12,000 women-years of use, with an overall Pearl Rate of 0.14. In large comparative multicenter trials, the average pregnancy rate during LNG-IUS use, within the first year has been 0.0-0.2%. The cumulative rate over 5 years has shown to be between 0.5% and 1.0%. These figures compare favorably with pregnancy rates of most contraceptive methods.

Up to half of pregnancies that occur with the LNG-IUS in place are **ectopic pregnancies.** Therefore if a woman becomes pregnant with the LNG-IUS, the possibility of an extra-uterine location must be considered and action

must be taken. Yet, because pregnancy rates are so very low, the actual number of ectopic pregnancies is only 1 per 1000 LNG-IUS users per year, or 0.01 per 100 woman-years (Bayer Schering Pharma, 2008). Additionally important to note for comparison purposes is the rate of ectopic pregnancy among sexually active women not using any method of contraception. The rate of ectopic pregnancy among these women has been recorded to be 1.2-1.6 per 100 women-years, significantly higher than the rate among women using LNG-IUS (Luukkainen and Pakarinen, 2006).

CONDITIONS REQUIRING PRECAUTIONS

Pregnancy: If the possibility of pregnancy cannot be ruled out when client is considering LNG-IUS use, insertion should be delayed until the woman's next menstrual period. The provider should assist the client in choosing another method in the mean time.
Pelvic Inflammatory Disease (PID): If the client is currently, recently or recurrently infected with PID, she should use condoms in addition to, or in place of, the LNG-IUS, as she is at high risk for STIs.
High risk for STIs: A woman with more than one partner or a woman with a partner who has multiple partners, should use condoms to prevent STIs, in addition to the LNG-IUS.
History of ectopic pregnancy: Women with prior ectopic pregnancies are at higher risk for recurrent ectopic pregnancies, and should be counseled about the warning signs for this condition.
Severe arterial disease or valvular heart disease: The LNG-IUS should not be the first contraceptive choice for women with these conditions. Antibiotic prophylaxis at time of insertion/removal of LNG-IUS should be considered when the patient suffers from valvular disease, to prevent the remote possibility of endocarditis.
Other anomalies and cancers of reproductive system: There are a range of gynecologic conditions that require precaution when considering, and possibly contraindicating, LNG-IUS use. Ensure a detailed review of medical history is included in patient counseling.

SIDE EFFECTS

Most side effects associated with LNG-IUS use are not serious. **Changes in menstrual bleeding patterns** are the most common side effect. Additionally, women using LNG-IUS occasionally develop **enlarged ovarian follicles** that rarely cause any symptoms. **Ectopic pregnancies** have occurred in LNG-IUS users, yet the device is actually protective against ectopic pregnancies. **Pelvic Inflammatory Disease (PID)** is a potential serious complication with LNG-IUS use and often requires device removal and antimicrobial medication, yet risk of PID may be smaller than with copper IUDs. In rare instances (less than 1 per 1000 insertions), **uterine perforation** takes place, which is mainly associated with improper insertion of device. Other conditions that may or may not be associated with LNG-IUS use include headaches, edema, breast tenderness, weight gain, vaginal discharge, cervicitis, dysmenorrhea, nervousness, depressive mood, mental lability, pelvic pain, nausea and acne.

BENEFITS AND LIMITATIONS TO LNG-IUS USE

Benefits of LNG-IUS use, additional to highly effective contraceptive action, include:

- A long-term reversible method
- No daily action required

- Easy insertion and removal (without the need for local anesthesia)
- Lowest dose of hormonal contraceptive, with no estrogen
- Lessening in frequency and amount of menstrual bleeding
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Limitations of use may include:

- Spotting and intermenstrual bleeding in first few months of use
- Possibility of hormonal side effects
- Insertion and removal to be done by a trained provider

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