

PATIENT INFORMATION BOOKLET

Liletta[®] 

(levonorgestrel-releasing
intrauterine system) **52 mg**

 **Allergan.**

Medicines[®]
360
♀

PATIENT INFORMATION

LILETTA (lye-LET-uh)

(levonorgestrel-releasing intrauterine system)

LILETTA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STIs).

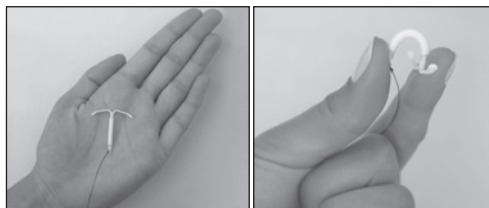
Read this Patient Information carefully before you decide if LILETTA is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about LILETTA, ask your healthcare provider. You should also learn about other birth control methods to choose the one that is best for you.

What is LILETTA?

- LILETTA is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 5 years.
- LILETTA can be removed by your healthcare provider at any time.
- LILETTA can be used whether or not you have given birth to a child.

LILETTA is a small, flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel (LNG) that is often used in birth control pills. Because LILETTA releases LNG into your uterus, only small amounts of the hormone enter your blood. LILETTA does not contain estrogen.

Two thin threads are attached to the stem (lower end) of LILETTA. The threads are the only part of LILETTA you can feel when LILETTA is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.



LILETTA is small

and flexible

What if I need birth control for more than 5 years?

LILETTA must be removed after 5 years. Your healthcare provider can place a new LILETTA during the same office visit if you choose to continue using LILETTA.

What if I want to stop using LILETTA?

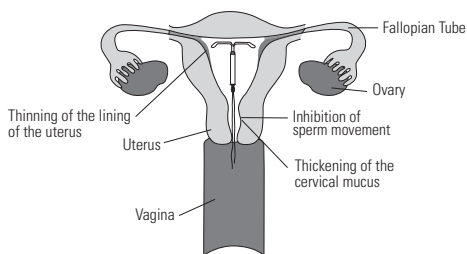
LILETTA is intended for use up to 5 years, but you can stop using LILETTA at any time by asking your healthcare provider to remove it. You could become pregnant as soon as LILETTA is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare provider about the best birth control methods for you, because your new method may need to be started 7 days before LILETTA is removed to prevent pregnancy.

What if I change my mind about birth control and want to become pregnant in less than 5 years?

Your healthcare provider can remove LILETTA at any time. You could become pregnant as soon as LILETTA is removed. About 6 out of 7 women who want to become pregnant will become pregnant sometime in the first year after LILETTA is removed.

How does LILETTA work?

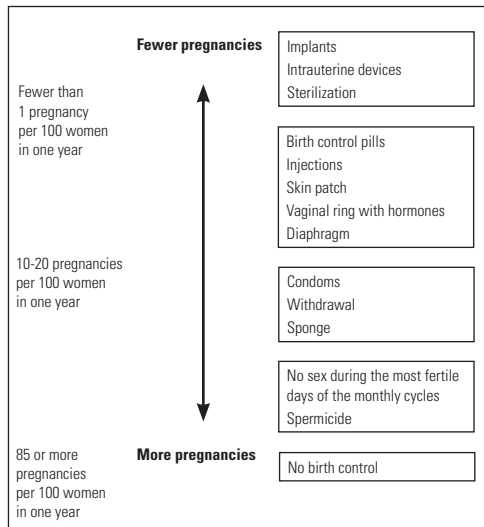
LILETTA may work in several ways including thickening cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.



How well does LILETTA work for contraception?

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.

LILETTA, an intrauterine system (IUS), is in the box at the top of the chart.



Who might use LILETTA?

You might choose LILETTA if you:

- want long-term birth control that provides a low chance of getting pregnant (less than 1 in 100)
- want birth control that works continuously for up to 5 years
- want birth control that is reversible
- want a birth control method that you do not need to take daily
- are willing to use a birth control method that is placed in the uterus
- want birth control that does not contain estrogen

Do not use LILETTA if you:

- are or might be pregnant; LILETTA cannot be used as an emergency contraceptive
- have a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis unless you have had a normal pregnancy after the infection went away
- have an untreated lower genital infection now
- have had an infection from an abortion within the last 3 months
- can get infections easily. For example, if you:
 - have problems with your immune system
 - have multiple sexual partners or your partner has multiple sexual partners
 - use or abuse intravenous drugs

- have or suspect you might have cancer of the uterus or cervix
- have bleeding from the vagina that has not been explained
- have short-term (acute) liver disease or liver tumor
- have breast cancer or any other cancer that is sensitive to progestin (a female hormone), now or in the past
- have an intrauterine system in your uterus already
- have a condition of the uterus that changes the shape of the uterine cavity, such as large fibroid tumors
- are allergic to levonorgestrel, silicone, polyethylene, or barium sulfate

Before having LILETTA placed, tell your healthcare provider if you have any medical conditions, including if you:

- have any of the conditions listed above
- have had a heart attack
- have had a stroke
- were born with heart disease or have problems with your heart valves
- have problems with blood clotting or take medicine to reduce clotting
- have high blood pressure
- recently had a baby or if you are breastfeeding
- have severe migraine headaches
- have severe or frequent headaches
- have AIDS, HIV, or any other sexually transmitted infection

How is LILETTA placed?

LILETTA is placed by your healthcare provider during an in-office visit.

First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a slim plastic tube containing LILETTA through the cervix into your uterus. Your healthcare provider will then remove the plastic tube, and leave LILETTA in your uterus. Your healthcare provider will trim the threads to the right length. Placement takes only a few minutes.

You may experience pain, bleeding, or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, LILETTA may not have been placed correctly. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.

Should I check that LILETTA is in place?

Yes, you should check that LILETTA is in proper position by feeling the threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that LILETTA is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the threads. Do not pull on the threads.

If you feel more than just the threads or if you cannot feel the threads, LILETTA may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that LILETTA is still in the right place.

How soon after placement of LILETTA should I return to my healthcare provider?

Call your healthcare provider if you have any questions or concerns (see "When should I call my healthcare provider?"). Otherwise, you should return to your healthcare provider for a follow-up visit 4 to 6 weeks after LILETTA is placed to make sure that LILETTA is in the right position.

Can I use tampons with LILETTA?

Yes, tampons may be used with LILETTA.

What if I become pregnant while using LILETTA?

Call your healthcare provider right away if you think you are pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using LILETTA, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy.

Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using LILETTA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labor, premature delivery, and even death can occur with pregnancies that continue with

an intrauterine system (IUS). Because of this, your healthcare provider may try to remove LILETTA, even though removing it may cause a miscarriage. If LILETTA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if LILETTA can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will LILETTA change my periods?

For the first 3 to 6 months, your period may become irregular and the number of bleeding days may increase. You may also have frequent spotting or light bleeding and cramping. Some women have heavy bleeding during this time. After you have used LILETTA for a while, the number of bleeding and spotting days is likely to lessen. For some women, menstrual periods will stop altogether. When LILETTA is removed, your menstrual periods will likely return to their former pattern.

Is it safe to breastfeed while using LILETTA?

You may use LILETTA when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, LILETTA is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills. The risk of LILETTA becoming attached to (embedded) or going through the wall of the uterus is increased when LILETTA is placed in breastfeeding women.

Will LILETTA interfere with sexual intercourse?

You and your partner should not feel LILETTA during intercourse. LILETTA is placed in the uterus, not in the vagina. In some cases, your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

Can I have an MRI with LILETTA in place?

LILETTA is MR Safe. It is safe to have an MRI following LILETTA placement.

What are the possible side effects of LILETTA?

LILETTA can cause serious side effects, including:

- **ectopic pregnancy.** If you get pregnant while using LILETTA, you might have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.
- **intrauterine pregnancy risks.** There are also risks if you get pregnant while using LILETTA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labor, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUS). Because of this, your healthcare provider may try to remove LILETTA, even though removing it may cause a miscarriage. If LILETTA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy. If, after seeing your healthcare provider, you choose to continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection. It is not known if LILETTA can cause long-term effects on the fetus if it stays in place during a pregnancy.
- **life-threatening infection.** Life-threatening infection can occur within the first few days after LILETTA is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after LILETTA is placed.
- **pelvic inflammatory disease (PID) or endometritis.** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID and endometritis are usually sexually transmitted. You have a higher chance of getting PID or endometritis if you or your partner has sex with other partners. PID or endometritis can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID or

endometritis may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID or endometritis can even cause death.

Tell your healthcare provider right away if you have any of these signs of PID or endometritis: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal pain, painful sex, chills, or fever.

- **perforation.** LILETTA may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, LILETTA may no longer prevent pregnancy. If perforation occurs, LILETTA may move outside the uterus and can cause internal scarring, infection, or damage to other organs. You may need surgery to have LILETTA removed if perforation or embedment occurs. The risk of perforation is increased in breastfeeding women.
- **expulsion.** LILETTA may come out of your uterus. This is called expulsion. Expulsion occurs in about 4 out of 100 women, most often in the first year of use. You may become pregnant if LILETTA comes out. If you think that LILETTA has come out, use another birth control method like condoms and spermicide or do not have sex (vaginal intercourse) until you are seen by a healthcare provider.
- **cysts on the ovary.** Some women using LILETTA develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 to 3 months. However, a cyst can cause pain and sometimes cysts will need surgery.
- **changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3 to 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.

The most common side effects of

LILETTA include:

• vaginal bacterial infection	• yeast infection of the outer part of your vagina (vulvovaginal)
• acne	• headache
• nausea or vomiting	• pain during sex
• abdominal pain	• breast pain
• pelvic pain	• depression
• weight increase	• vaginal discharge
• mood changes	• anxiety

• **Pain, bleeding, or dizziness during and after placement.**

If these symptoms do not stop within 30 minutes after placement, LILETTA may not have been placed correctly, or they may be symptoms of perforation or expulsion. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.

- **Missed menstrual periods.** About 2 out of 10 women stop having periods after 1 year of LILETTA use. If you do not have a period for 6 weeks during LILETTA use, call your healthcare provider. If you have any concerns that you may be pregnant while using LILETTA, do a urine pregnancy test and call your healthcare provider. When LILETTA is removed, your menstrual periods will usually return to your previous pattern.

These are not all the possible side effects of LILETTA. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Allergan at 1-800-678-1605.

After LILETTA has been inserted, when should I call my healthcare provider?

Call your healthcare provider if you have any concerns about LILETTA. Be sure to call if you:

- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores

- have unexplained fever, flu-like symptoms or chills
- might be exposed to sexually transmitted infections (STIs)
- are concerned that LILETTA may have been expelled (came out)
- cannot feel LILETTA's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes. These may be signs of liver problems
- have had a stroke or heart attack
- you or your partner becomes HIV positive
- have severe vaginal bleeding, bleeding that lasts a long time, or you miss your period

General information about the safe and effective use of LILETTA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

You can ask your pharmacist or healthcare provider for information about LILETTA that is written for health professionals.

For more information, go to www.LILETTA.com or call 1-855-LILETTA (1-855-545-3882).

This Patient Information has been approved by the U.S. Food and Drug Administration.

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(levonorgestrel-releasing intrauterine system) **52 mg**

Consent Form

I have read the patient information booklet and my healthcare provider has answered my questions about LILETTA. I choose to have LILETTA inserted by

Healthcare provider's name

Patient's signature

Date

The patient has signed this consent form in my presence and I have provided counseling to her and answered her questions regarding LILETTA.

Healthcare provider's signature

Date

LILETTA must be removed or replaced after 5 years.

LILETTA is scheduled for removal on _____

Date



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Follow-up Reminder Card

Bring this card with you to each of your scheduled appointments. Your healthcare provider will update the appointment information on this card, including the date of your next visit.