Ask your doctor if LILETTA may be right for you.

*LILETTA is an intrauterine system, or IUS, otherwise known as an IUD, intrauterine device.

**INDICATION**

LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg is a hormone-releasing system placed in your uterus to prevent pregnancy for as long as you want for up to 6 years.

Please see Important Risk Information throughout and accompanying Brief Summary.
**WHAT IS LILETTA®?**

LILETTA is a small, flexible, plastic, T-shaped device. When placed in the uterus, it slowly releases a progestin hormone called levonorgestrel—the same kind of hormone that is often used in birth control pills.

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

**HOW EFFECTIVE IS LILETTA®?**

>99% effective in preventing pregnancy for up to 6 years

LILETTA has been found to be more than 99% effective at preventing pregnancy for up to 6 years in different types of women of childbearing age. It can be used by women who have had children and women who have never been pregnant.

**IMPORTANT RISK INFORMATION ABOUT LILETTA**

- **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 (PID occurs in less than 1% of users)
  - Have an untreated lower genital infection now
  - Have had an infection from an abortion within the last 3 months

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

A backup birth control method, such as condoms and spermicide, may need to be used for 7 days after LILETTA insertion to prevent pregnancy.

Please see Important Risk Information throughout and accompanying Brief Summary.
BIRTH CONTROL METHODS BASED ON PREGNANCIES PER YEAR

FEWER PREGNANCIES

- FEWER THAN 1 PREGNANCY PER 100 WOMEN IN 1 YEAR
  - INTRAUTERINE DEVICES
  - INJECTIONS
  - IMPLANTS
  - STERILIZATION
  - SKIN PATCH

- 10-20 PREGNANCIES PER 100 WOMEN IN 1 YEAR
  - BIRTH CONTROL PILLS
  - VAGINAL RING WITH HORMONES
  - DIAPHRAGM

- 85 OR MORE PREGNANCIES PER 100 WOMEN IN 1 YEAR
  - CONDOMS
  - WITHDRAWAL
  - SPONGE
  - SPERMICIDE

- NO SEX DURING MOST FERTILE DAYS OF MONTHLY CYCLE

MORE PREGNANCIES

- NO BIRTH CONTROL

IMPORTANT RISK INFORMATION ABOUT LILETTA® (continued)

- Do not use LILETTA if you (continued):
  - 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

Please see Important Risk Information throughout and accompanying Brief Summary.
How does Liletta® work?

Liletta may work in several ways, including:

- Thickening cervical mucus
- Inhibiting sperm movement
- Reducing sperm survival
- Thinning the lining of your uterus

It is not known exactly how these actions work together to prevent pregnancy.

Terms to know

**Cervical mucus:** Fluid or gel-like discharge from the cervix. The thickness and amount of cervical mucus change throughout your menstrual cycle, especially when you are ovulating.

**Sperm:** The male reproductive cells that have the potential to fertilize an egg from a female.

**Uterine lining:** The inner layer of the uterus (womb). This tissue normally sheds monthly when an egg is not fertilized by sperm.

**Cervix:** The narrow opening of the uterus, which connects the uterus to the vagina.

**Fallopian tube:** One of two narrow tubes that carries an egg from the ovary to the uterus.

**Ovary:** One of two reproductive organs that stores eggs in a woman’s body.

**Uterus:** An organ of the female reproductive system, also called the womb, where the lining sheds during your menstrual cycle if pregnancy doesn’t occur.

**Vagina:** A muscular canal that connects the uterus and cervix to the outside of your body, allowing for menstruation, intercourse, and childbirth.

**Liletta® threads:** Two thin threads attached to the lower end of Liletta. The threads are the only part of Liletta you should feel when Liletta is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.

Important risk information about Liletta (continued)

- Call your healthcare provider right away if you think you are pregnant. If you get pregnant while using Liletta, you may have an ectopic pregnancy, which means 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 can cause internal bleeding. There are also risks if you get pregnant while using Liletta and the pregnancy is in the uterus. Severe infection and premature labor or delivery can occur with pregnancies that continue with an IUS.

- Although uncommon, pregnancy while using Liletta can be life threatening and may result in loss of pregnancy or fertility.

- Bleeding and spotting may increase in the first 3 to 6 months and remain irregular. Periods over time usually become shorter, lighter or may stop.

Please see Important Risk Information throughout and accompanying Brief Summary.
WHAT TO EXPECT FROM LILETTA®

After LILETTA is inserted

After LILETTA is inserted, your healthcare provider will explain how you can check the threads, once a month, to make sure LILETTA is still in place. Schedule a follow-up appointment with your healthcare provider 4 to 6 weeks after placement and at least once per year thereafter.

TO LEARN MORE, VISIT LILETTA.COM.

WILL IT AFFECT MY PERIOD?

For the first 3 to 6 months, your period may become a little unpredictable and you may bleed more than usual. 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 days you experience bleeding and spotting is likely to lessen. For some women, menstrual periods may stop altogether. When LILETTA is removed, your menstrual periods will likely return to their former pattern.

If you have any concerns that you may be pregnant while using LILETTA, call your healthcare provider and, if possible, also do a urine pregnancy test.

WILL MY PARTNER FEEL IT DURING SEX?

LILETTA should not be felt during sexual intercourse because it’s placed in the uterus, not the vagina. However, there is a chance that male partners may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

IMPORTANT RISK INFORMATION ABOUT LILETTA (continued)

• 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.

WHAT IF MY PLANS CHANGE?

LILETTA® is a reversible type of birth control

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. About 6 out of 7 women who want to become pregnant will become pregnant sometime in the first year after LILETTA is removed.

If you do not wish to become pregnant, you should use another method of birth control as soon as LILETTA is removed. 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.

LILETTA IS INTENDED FOR USE UP TO 6 YEARS

ASK YOUR DOCTOR IF LILETTA IS RIGHT FOR YOU.

IMPORTANT RISK INFORMATION ABOUT LILETTA (continued)

• Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. These 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. 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.

Please see Important Risk Information throughout and accompanying Brief Summary.
TALK TO YOUR HEALTHCARE PROVIDER

While you’re considering LILETTA® as your method of birth control, you and your healthcare provider should discuss your health in general.

When speaking with your healthcare provider, it’s important that you mention:

- Any heart problems you have or have had
- If you’ve had a baby recently or are breastfeeding
- Any medicines you’re taking, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- If you have any sexually transmitted diseases (STDs) or sexually transmitted infections (STIs)

A UNIQUE COLLABORATION

AbbVie (the maker of LILETTA®) has a groundbreaking partnership with Medicines360®, a nonprofit women’s health pharmaceutical company, to expand access to LILETTA regardless of income or insurance coverage.

- AbbVie is investing in innovative programs and solutions that facilitate access in both public and private sectors
- Medicines360 invests their proceeds in advocacy, education, and additional product and partnership development to further their mission in the U.S. and globally

For more information about LILETTA, go to LILETTA.com or call 1-855-LILETTA (1.855.545.3882).

IMPORTANT RISK INFORMATION ABOUT LILETTA (continued)

- LILETTA may partially go into (become embedded) or go completely through (perforate) the wall of the uterus. 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 it is embedded or perforation occurs. Risk of perforation is increased in breastfeeding women

FOR A LIST OF QUESTIONS TO ASK YOUR HEALTHCARE PROVIDER, GO TO LILETTA.COM.
INDICATION

LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg is a hormone-releasing system placed in your uterus to prevent pregnancy for as long as you want for up to 6 years.

IMPORTANT RISK INFORMATION

ABOUT LILETTA (continued)

• LILETTA may come out of your uterus (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

• Ovarian cysts may occur but usually disappear

*LILETTA does not protect against HIV or STDs.

Available by prescription only.

Please see Important Risk Information throughout and accompanying Brief Summary.
LILETTA® (levonorgestrel-releasing intrauterine system) 52 mg

Read the full 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. 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.

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

What is LILETTA?
LILETTA is a hormone-releasing system placed in your uterus to prevent pregnancy for up to 6 years. LILETTA is T-shaped. It is made of flexible plastic and contains a hormone called levonorgestrel. Levonorgestrel is a progestin hormone often used in birth control pills, however, unlike many birth control pills, LILETTA does not contain estrogen.

LILETTA releases the hormone into the uterus. Only small amounts of the hormone enter your blood.

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.

What if I need birth control for more than 6 years?
LILETTA must be removed after 6 years, but your healthcare provider can place a new LILETTA during the same office visit if you choose to continue using LILETTA.

What if I change my mind about birth control and want to become pregnant in less than 6 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?
It is not known exactly how LILETTA works. LILETTA may work in several ways. It may thicken your cervical mucus, thin the lining of your uterus, inhibit sperm movement and reduce sperm survival. LILETTA may stop release of your egg from your ovary, but this is not the way it works in most cases. Most likely, 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.

LILETTA, an intrauterine system (IUS), is also known as an intrauterine device (IUD), which is described in the box at the top of the chart. The box at 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.

Who might use LILETTA?
You might choose LILETTA if you:
- need birth control that is highly effective
- need birth control that is reversible

Who should not use LILETTA?
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 more than one sexual partner or your partner has more than one partner
  - have problems with your immune system
  - have leukemia
  - have AIDS
  - 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 or have had any medical conditions, including those listed below:
- any of the conditions listed above
- a heart attack
- a stroke
- been born with heart disease or have problems with your heart valves
- problems with blood clotting or take medicine to reduce clotting
- high blood pressure
- recently had a baby or if you are breastfeeding
- severe migraine headaches
- severe or frequent headaches
- AIDS, HIV, or any other sexually transmitted infection

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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 remove the plastic tube, and leave LILETTA in your uterus. Your healthcare provider will trim the threads to the right length.

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. First, wash your hands with soap and water. Feel for the threads at the top of your vagina with your clean fingers. The threads are the only part of LILETTA you can feel when LILETTA is in your uterus. Do not pull on the threads. If you feel more than 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 “After LILETTA has been inserted, 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.
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 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 decrease, and you may even find that your periods 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 progester-only birth control pills. The risk of LILETTA becoming attached to (embedded) or going through (perforation) 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.

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.

• 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 partially go into the wall of the uterus (become embedded) or go completely through the wall of the uterus (perforate). 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 it is embedded or perforation occurs. The risk of perforation is increased in breastfeeding women.

• Expulsion. LILETTA may come out of your uterus (expulsion). 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.

Common side effects of LILETTA include:

• Vaginal bacterial infection, yeast infection of the outer part of your vagina, acne, headache, nausea or vomiting, pain during sex, abdominal pain, breast pain, pelvic pain, depression, increased weight, vaginal discharge, mood changes, anxiety, back pain, and menstrual-like cramping.

• 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.

This is not a complete list of possible side effects of LILETTA. For more information, ask your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to Allergan at 1-800-678-1605, or FDA at 1-800-FDA-1088.

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 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

Need More Information?
• This summary contains important risk information about LILETTA. The information provided here is not comprehensive, and is not meant to take the place of your healthcare provider's instructions. To learn more, talk about LILETTA with your healthcare provider or pharmacist.

• The FDA-approved product labeling can be found at www.LILETTA.com or call 1-855-LILETTA (1-855-545-3882).

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