

# A Commitment to Patient Savings



## Two Helpful Programs

Read more inside



### 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 3 years.

**Please see Important Risk Information throughout and enclosed Brief Summary.**

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

# Savings from the start



Liletta  
**Patient  
Savings**  
Program<sup>SM</sup>

If you decide to get LILETTA: eligible patients may pay no more than \$75 for the LILETTA product, up to a maximum savings limit of \$500.\*†



Visit  
**LILETTAcard.com**  
or call  
**1.855.706.4508**  
to enroll

\*Depending on your insurance coverage, eligible patients may pay no more than \$75 for the LILETTA product up to a maximum savings limit of \$500. Offer applies to product only, and does not apply to costs associated with medical examination or product administration. Check with your pharmacist or healthcare provider for copay discount. Patient out-of-pocket expense may vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Program expires 12/31/17. **Please see Program Terms and Conditions on page 8 of this brochure or at LILETTAcard.com.**

†LILETTA may be covered under your insurance plan's medical or pharmacy benefit.



## In order to participate in the LILETTA Patient Savings Program<sup>SM</sup>, you must:

- Have commercial prescription drug insurance†
- Not participate in Medicaid, Medicare, TRICARE, or any other federal or state healthcare program (including state pharmaceutical assistance programs)
- Have an out-of-pocket expense for LILETTA that is greater than \$75
- Live in the U.S. or Puerto Rico
- Agree to comply with the **LILETTA Patient Savings Program** Terms and Conditions, which can be found on page 8 of this brochure

**Once enrolled, eligible patients will receive a debit card in the mail with instructions for activation.**



## 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 had a serious pelvic infection called pelvic inflammatory disease (PID), unless you have had a normal pregnancy after the infection went away (PID occurs in less than 1% of users)

**Please see Important Risk Information throughout and enclosed Brief Summary.**

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# Savings when continuing with LILETTA

Liletta   
+ Liletta

Patient Commitment  
Program<sup>SM</sup>

When the time comes, eligible patients wishing to continue with LILETTA may obtain a second LILETTA product at no out-of-pocket cost, up to a maximum savings limit of \$700.\*†



Enroll  
by registering at

[LILETTAcard.com](http://LILETTAcard.com)

or calling

1.855.706.4508

A representative will be there  
between 9 AM–8 PM ET  
(Monday through Friday)  
to assist you

\*Depending on insurance coverage, eligible patients who received their first LILETTA on or before December 31, 2017, may have their out-of-pocket cost for a second LILETTA reduced to \$0, up to a maximum savings limit of \$700. Offer applies to product only, and does not apply to costs associated with medical examination or product administration. Check with pharmacist or healthcare provider for copay discount. Patient out-of-pocket expense may vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs.

**Please see LILETTA + LILETTA Patient Commitment Program Terms and Conditions on page 9 of this brochure or at [LILETTAcard.com](http://LILETTAcard.com).**

†LILETTA may be covered under your insurance plan's medical or pharmacy benefit.



## In order to participate in the LILETTA + LILETTA Patient Commitment Program<sup>SM</sup>, you must:

- Have commercial health insurance†
- Not participate in Medicare, Medicaid, or any other federal or state healthcare program (including state pharmaceutical assistance programs)
- Be currently using your first LILETTA, which you received on or before December 31, 2017
- Live in the U.S. or Puerto Rico
- Agree to comply with the **LILETTA + LILETTA Patient Commitment Program** Terms and Conditions, which can be found on page 9 of this brochure

## Important Risk Information about LILETTA (continued)

- Do not use LILETTA if you (continued):
  - Have an untreated pelvic infection now
  - Have had a serious pelvic infection in the past 3 months after a pregnancy
  - 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

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# Important Risk Information

## Important Risk Information about LILETTA (continued)

- Do not use LILETTA if you (continued):
  - Have bleeding from the vagina that has not been explained
  - Have 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 (IUS) 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
- 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. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain 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 delivery can occur with pregnancies that continue with an intrauterine system (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
- Life-threatening infection can occur within the first few days after LILETTA is inserted. Call your healthcare provider immediately if you develop severe pain or fever shortly after LILETTA is inserted
- Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID). PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID can cause serious problems such as infertility, ectopic pregnancy or pelvic pain that does not go away. More serious cases of PID may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID can even cause death. Tell your healthcare provider right away if you have any of these signs of PID: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal pain, painful sex, chills, or fever

**Please see Important Risk Information throughout and enclosed Brief Summary.**

**Liletta**   
(levonorgestrel-releasing  
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# Terms & Conditions

## LILETTA Patient Savings Program<sup>SM</sup>

1. This offer is good for use only with a LILETTA (levonorgestrel-releasing intrauterine system) 52 mg prescription at the time the prescription is filled or after the product is administered to the patient. 2. Depending on your insurance coverage, eligible patients may pay no more than \$75 for the LILETTA product up to a maximum savings limit of \$500. Check with your pharmacist or healthcare provider for your copay discount. Patient out-of-pocket expense may vary. 3. This offer is not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs, or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this offer if they are Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees. This offer is not valid for cash-paying patients. 4. Each card is valid for one LILETTA prescription, which must be filled or administered to the patient before the program expires on 12/31/17. Savings requests must be submitted to LILETTAcard.com or faxed to 1.888.683.4991 within 60 days after the prescription is filled and the product is administered to the patient. 5. Allergan reserves the right to rescind, revoke, or amend this offer without notice. 6. Offer good only in the USA, including Puerto Rico, at participating pharmacies or healthcare providers. 7. Void where prohibited by law, taxed, or restricted. 8. This card is not transferable. The selling, purchasing, trading, or counterfeiting of this card is prohibited by law. 9. This card has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer for the specified prescription. 10. This offer is not health insurance. 11. This card expires December 31, 2017. 12. **By redeeming this card, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer.**

**For assistance, please call 1.855.706.4508 Monday through Friday 9 AM–8 PM (except holidays). For healthcare provider or pharmacist assistance, please call the 24 hr/7 day a week help desk at 1.866.242.9104.**

Program managed by The Macaluso Group on behalf of Allergan.

**Please see Important Risk Information throughout and enclosed Brief Summary.**





## LILETTA + LILETTA Patient Commitment Program<sup>SM</sup>

**1.** This offer is good for use only by eligible patients who received their first LILETTA on or before December 31, 2017 and who have a valid prescription for a second LILETTA, at the time the second prescription is filled or after the second LILETTA is administered to the patient. **2.** Depending on your insurance coverage, eligible patients wishing to continue with LILETTA may have their out-of-pocket cost reduced to \$0 for a second LILETTA, up to a maximum savings limit of \$700. Offer applies to product only, and does not apply to costs associated with medical examination or product administration. Check with your pharmacist or healthcare provider for your copay discount. Patient out-of-pocket expense may vary. **3.** This offer is not valid for patients who, at the time they received their first or second LILETTA, were enrolled in Medicare, Medicaid, or other federal or state healthcare programs, or private indemnity or HMO insurance plans that reimburse you for the entire cost of your prescription drugs. Patients may not use this offer if, at the time they received their first or second LILETTA, they were Medicare-eligible and enrolled in an employer-sponsored health plan or medical or prescription drug benefit program for retirees. This offer is also not valid for patients who were cash-paying patients at the time they received their first or second LILETTA. **4.** This offer is valid for one LILETTA prescription, which must be for a second LILETTA for a patient wishing to continue with LILETTA, and must be filled or administered to the patient before the program expires on 12/31/21. Patients must enroll at [LILETTAcard.com](http://LILETTAcard.com) or by calling 1.855.706.4508 within 60 days after receiving their first LILETTA, providing Explanation of Benefits (EOB) documentation. Savings requests and required EOB documentation for the second LILETTA must be submitted to [LILETTAcard.com](http://LILETTAcard.com) or faxed to 1.888.683.4991 within 60 days after the second LILETTA prescription is filled and the second LILETTA is administered to the patient. **5.** Allergan reserves the right to rescind, revoke, or amend this offer without notice. **6.** Offer good only in the USA, including Puerto Rico, at participating pharmacies or healthcare providers. **7.** Void where prohibited by law, taxed, or restricted. **8.** This offer is not transferable. The selling, purchasing, trading, or counterfeiting of this card is prohibited by law. **9.** This offer has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer for the specified prescription. **10.** This offer is not health insurance. **11.** This offer expires December 31, 2021. **12. By redeeming this offer, you acknowledge that you are an eligible patient and that you understand and agree to comply with the terms and conditions of this offer.**

**For assistance, please call  
1.855.706.4508 Monday through  
Friday 9 AM–8 PM (except holidays).**

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# A Commitment to Patient Savings



## Two Helpful Programs

Liletta  
**Patient  
Savings**  
Program<sup>SM</sup>

Liletta  
**+ Liletta**  
Patient Commitment  
Program<sup>SM</sup>

We're here to help. Visit [LILETTAcard.com](http://LILETTAcard.com)  
or call 1.855.706.4508 for additional support.

### Important Risk Information about LILETTA (continued)

- LILETTA may come out of your uterus. This is called expulsion. Expulsion occurs in about 3 out of 100 women. 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 enclosed Brief Summary.**



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Liletta<sup>®</sup>   
(levonorgestrel-releasing  
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## Brief Summary of Patient Information

### LILETTA (levonorgestrel-releasing intrauterine system)

#### LILETTA is used to prevent pregnancy. LILETTA does not protect against HIV infection (AIDS) and other sexually transmitted infections (STDs).

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 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 inserted in your uterus to prevent pregnancy for up to 3 years. LILETTA is T-shaped. It is made of flexible plastic and contains a progestin 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 3 years?

LILETTA must be removed after 3 years, but your healthcare provider can insert 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 3 years?

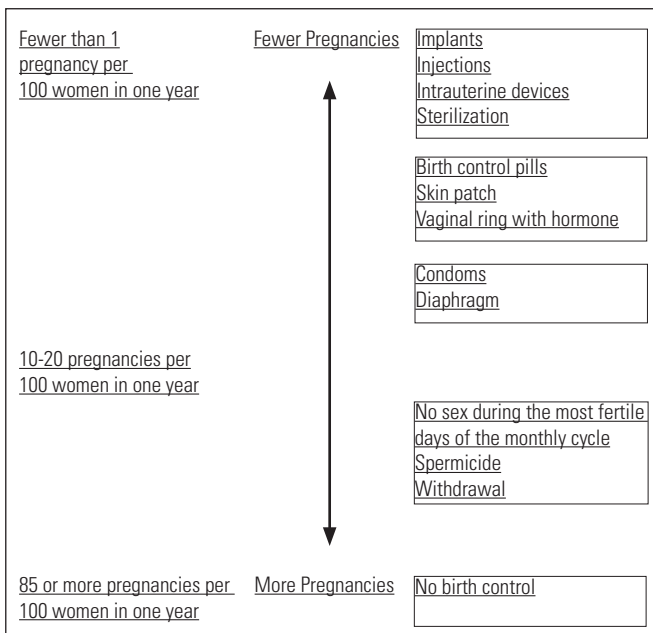
Your healthcare provider can remove LILETTA at any time. You could become pregnant as soon as LILETTA is removed. About 5 out of 6 women who want to become pregnant will become pregnant sometime in the first year after LILETTA is removed.

#### 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 in the box 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.



#### 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 had a serious pelvic infection called pelvic inflammatory disease (PID) unless you have had a normal pregnancy after the infection went away
- have an untreated pelvic infection now
- have had a serious pelvic infection in the past 3 months after a pregnancy

- 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 liver disease or liver tumor
- have or suspect you 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

#### How is LILETTA inserted?

LILETTA is inserted 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 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. Insertion takes only a few minutes.

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 inserted correctly. Your healthcare provider will examine you to see if LILETTA needs to be removed or replaced.

#### Before having LILETTA inserted, tell your healthcare provider if you:

- 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
- are or might be pregnant
- have acute pelvic inflammatory disease or a history of pelvic inflammatory disease
- have AIDS, HIV, or any other sexually transmitted infection
- have any other medical conditions

#### 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 should feel when LILETTA is inside your uterus. Be careful not to pull on the threads. If you feel more than the threads, LILETTA is not in the right position and may not prevent pregnancy. If you cannot feel the threads at all, ask your healthcare provider to check that LILETTA is still in the right position. In either case, use a non-hormonal birth control method (such as condoms and spermicide) until otherwise advised by your healthcare provider.

#### How soon after insertion 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 inserted 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 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 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 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. Some women have heavy bleeding during this time. After you have used LILETTA for a while, the number of bleeding and spotting days are likely to decrease, and you may even find that your periods stop altogether.

### 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.

### Will LILETTA interfere with sexual intercourse?

You and your partner should not feel LILETTA during intercourse. LILETTA is inserted in the uterus, not in the vagina. Sometimes male partners feel the threads.

### What are the possible side effects of using LILETTA?

The following are serious side effects of LILETTA

- **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 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 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 inserted. Call your healthcare provider immediately if you develop severe pain or fever shortly after LILETTA is inserted.
- **Pelvic inflammatory disease (PID).** Some IUS users get a serious pelvic infection called pelvic inflammatory disease (PID). PID is usually sexually transmitted. You have a higher chance of getting PID if you or your partner has sex with other partners. PID 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 may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID can even cause death.

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

- **Perforation.** LILETTA may go through the uterus. This is called perforation. If your uterus is perforated, LILETTA may no longer prevent pregnancy. It may move outside the uterus and can cause internal scarring, infection, or damage to other organs and you may need surgery to have LILETTA removed. The risk of perforation is increased in breastfeeding women.
- **Expulsion.** LILETTA may come out of your uterus by itself. This is called expulsion. You may become pregnant if LILETTA comes out. If you notice LILETTA has come out, use another birth control, like condoms and spermicide, or do not have sex (vaginal intercourse) until you are seen by a healthcare provider.

### Common side effects of LILETTA include:

- Vaginal infection, infection of the outer part of your vagina, acne, headache, nausea/vomiting, pain during sex, abdominal pain, breast pain, pelvic pain, depression, and mood changes.
- **Discomfort during placement.** Dizziness, faintness, bleeding or cramps may occur during placement. This is common. Let your healthcare provider know if the cramping is severe. If these symptoms do not stop within 30 minutes after insertion, LILETTA may not have been inserted correctly.
- **Missed menstrual periods.** About 1 out of 5 women stop having periods after 1 year of LILETTA use. If you have any concerns that you may be pregnant while using LILETTA, call your healthcare provider. When LILETTA is removed, your menstrual periods will usually return to your previous pattern.
- **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 if the bleeding becomes heavy after it has been light for a while.
- **Cyst on the ovary.** Some women using LILETTA develop a cyst on the ovary. These cysts usually disappear on their own in two to three months. However, cysts can cause pain and sometimes cysts will need surgery.

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 Actavis at 1-800-272-5525, 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 or bleeding that concerns you
- Miss a menstrual period

### General advice about prescription medicines

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. This leaflet summarizes the most important information about LILETTA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider for information about LILETTA that is written for health professionals.

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