

FDA-Approved Patient Labeling

Patient Information Kyleena (Ki-lee-nah)

(levonorgestrel-releasing intrauterine system)

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

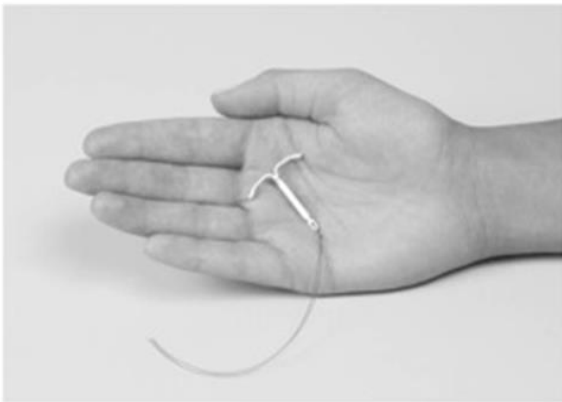
Read this Patient Information carefully before you decide if Kyleena is right for you. This information does not take the place of talking with your gynecologist or other healthcare provider who specializes in women's health. If you have any questions about Kyleena, ask your healthcare provider. You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

What is Kyleena?

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

Kyleena 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 Kyleena releases LNG into your uterus, only small amounts of the hormone enter your blood. Kyleena does not contain estrogen.

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



Kyleena is small



and Flexible

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

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

What if I want to stop using Kyleena?

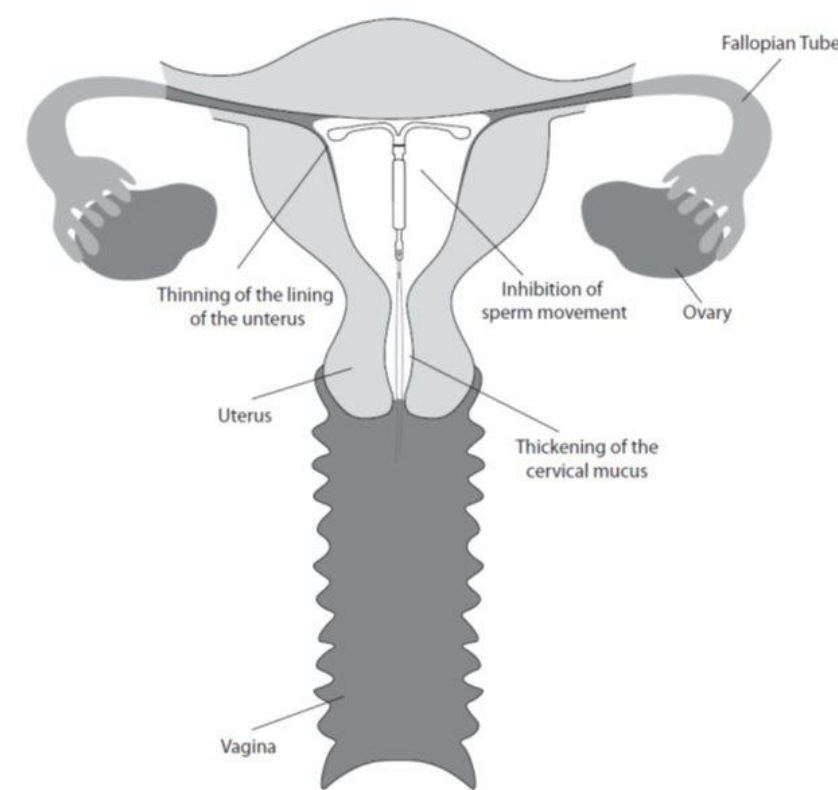
Kyleena is intended for use up to 5 years, but you can stop using Kyleena at any time by asking your healthcare provider to remove it. You could become pregnant as soon as Kyleena is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare provider about the best birth control methods for you, because your new method may need to be started 7 days before Kyleena 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 Kyleena at any time. You may become pregnant as soon as Kyleena is removed. About 7 out of 10 women who want to become pregnant will become pregnant sometime in the first year after Kyleena is removed.

How does Kyleena work?

Kyleena 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.

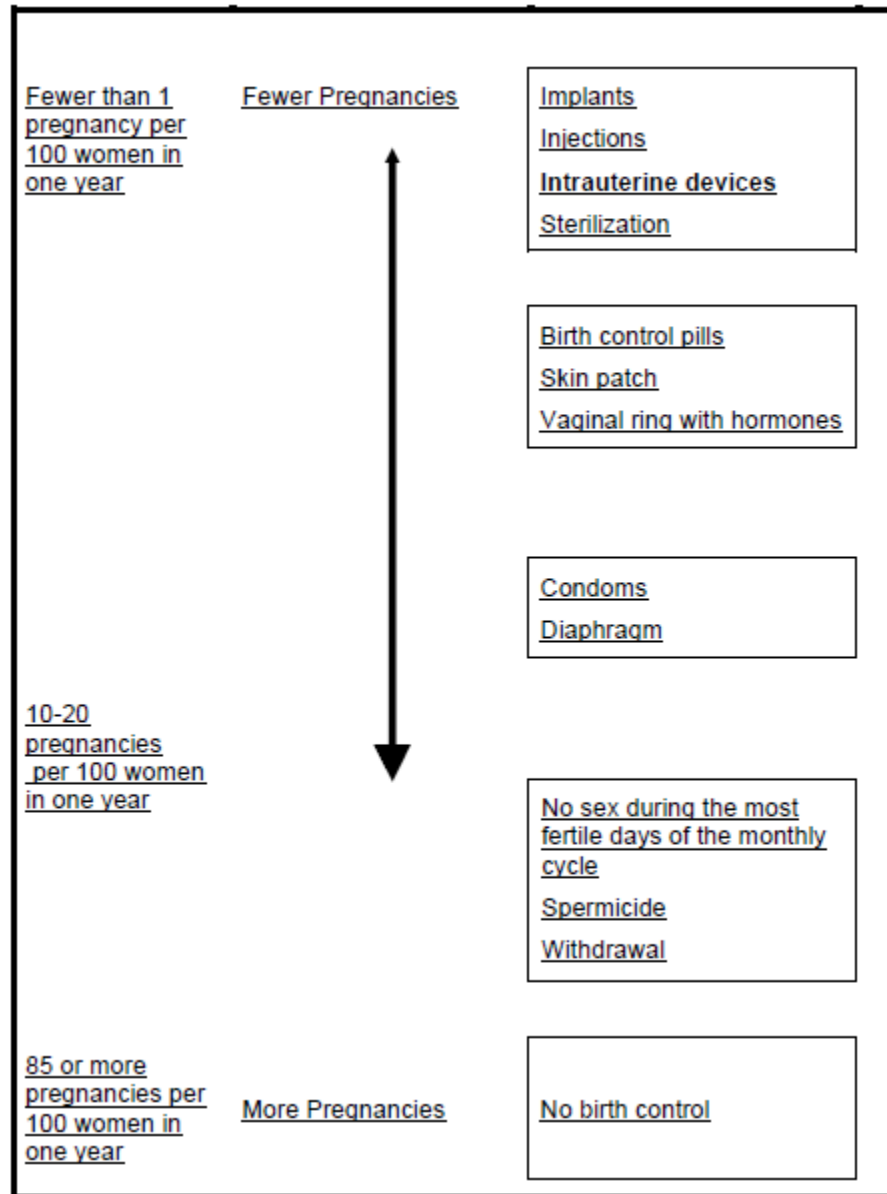


How well does Kyleena work for contraception?

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.

Kyleena, an intrauterine device (IUD), is in the box at the top of the chart.



Who might use Kyleena?

You might choose Kyleena 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 Kyleena if you:

- Are or might be pregnant; Kyleena 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 multiple sexual partners or your partner has multiple sexual partners
 - Have problems with your immune system
 - 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 a 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 device 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, silver, silica, barium sulfate, polypropylene, or copper phthalocyanine

Before having Kyleena placed, tell your healthcare provider 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 are breastfeeding
- Have severe migraine headaches

How is Kyleena placed?

Kyleena 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 Kyleena into your uterus. Your healthcare provider will then remove the plastic tube, and leave Kyleena in your uterus. Your healthcare provider will cut 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, Kyleena may not have been placed correctly. Your healthcare provider will examine you to see if Kyleena needs to be removed or replaced.

Should I check that Kyleena is in place?

Yes, you should check that Kyleena is in proper position by feeling the removal threads. It is a good habit to do this 1 time a month. Your healthcare provider should teach you how to check that Kyleena 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 removal threads. Do not pull on the threads. If you feel more than just the threads or if you cannot feel the threads, Kyleena 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 Kyleena is still in the right place.

How soon after placement of Kyleena 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 Kyleena is placed to make sure that Kyleena is in the right position.

Can I use tampons with Kyleena?

Yes, tampons may be used with Kyleena.

What if I become pregnant while using Kyleena?

Call your healthcare provider right away if you think you may be pregnant. If possible, also do a urine pregnancy test. If you get pregnant while using Kyleena, 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 Kyleena and the pregnancy is in the uterus. Severe infection, miscarriage, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). Because of this, your healthcare provider may try to remove Kyleena, even though removing it may cause a miscarriage. If Kyleena 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 Kyleena can cause long-term effects on the fetus if it stays in place during a pregnancy.

How will Kyleena 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. Some women have heavy bleeding during this time. After you have used Kyleena for a while, the number of bleeding and spotting days is likely to lessen. For some women, periods will stop altogether. When Kyleena is removed, your menstrual periods should return.

Is it safe to breastfeed while using Kyleena?

You may use Kyleena when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, Kyleena 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 Kyleena becoming attached to (embedded) or going through the wall of the uterus is increased when Kyleena is placed in breastfeeding women.

Will Kyleena interfere with sexual intercourse?

You and your partner should not feel Kyleena during intercourse. Kyleena is placed in the uterus, not in the vagina. Sometimes 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 Kyleena in place?

Kyleena can be safely scanned with MRI only under specific conditions. Before you have an MRI, tell your healthcare provider that you have Kyleena, an intrauterine device (IUD), in place.

What are the possible side effects of Kyleena?

Kyleena can cause serious side effects, including:

- **Ectopic pregnancy and intrauterine pregnancy risks.** There are risks if you become pregnant while using Kyleena (see "What if I become pregnant while using Kyleena?").
- **Life-threatening infection.** Life-threatening infection can occur within the first few days after Kyleena is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after Kyleena is placed.
- **Pelvic inflammatory disease (PID).** Some IUD users get a serious pelvic infection called pelvic inflammatory disease. 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. A hysterectomy (removal of the uterus) 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 (stomach area) pain, painful sex, chills, or fever.

- **Perforation.** Kyleena may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If this occurs, Kyleena may no longer prevent pregnancy. If perforation occurs, Kyleena may move outside the uterus and can cause internal scarring, infection, or damage to other organs. You may need surgery to have Kyleena removed. The risk of perforation is increased when Kyleena is placed in breastfeeding women.

Common side effects of Kyleena include:

- **Pain, bleeding or dizziness during and after placement.** If these symptoms do not stop 30 minutes after placement, Kyleena may not have been placed correctly. Your healthcare provider will examine you to see if Kyleena needs to be removed or replaced.

- **Expulsion.** Kyleena may come out by itself. This is called expulsion. Expulsion occurs in about 4 out of 100 women. You may become pregnant if Kyleena comes out. If you think that Kyleena has come out, use a backup birth control method like condoms and spermicide and call your healthcare provider.
- **Missed menstrual periods.** About 12 out of 100 women stop having periods after 1 year of Kyleena use. If you do not have a period for 6 weeks during Kyleena use, call your healthcare provider. When Kyleena is removed, your menstrual periods should return.
- **Changes in bleeding.** You may have bleeding and spotting between menstrual periods, especially during the first 3–6 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.
- **Cysts on the ovary.** About 22 out of 100 women using Kyleena 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.

Other common side effects include:

- Inflammation or infection of the outer part of your vagina (vulvovaginitis)
- Abdomen or pelvic pain
- Headache or migraine
- Acne or greasy skin
- Painful periods
- Sore or painful breasts

This is not a complete list of possible side effects with Kyleena. For more information, ask your healthcare provider. Tell your healthcare provider if you have any side effect that bothers you or does not go away.

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 the manufacturer at 1-888-842-2937, or www.fda.gov/medwatch.

After Kyleena has been placed, when should I call my healthcare provider?

If Kyleena is accidentally removed and you had vaginal intercourse within the preceding week, you may be at risk of pregnancy, and you should talk to a healthcare provider.

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

- Think you are pregnant
- Have pelvic pain, abdominal 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 Kyleena may have been expelled (came out)

- Cannot feel Kyleena'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
- Become HIV positive or your partner becomes HIV positive
- Have severe vaginal bleeding or bleeding that concerns you

General advice about the safe and effective use of Kyleena.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. You can ask your healthcare provider for information about Kyleena that is written for healthcare providers.

For more information, go to www.Kyleena.com or call 1-888-842-2937.

Manufactured for: Bayer HealthCare Pharmaceuticals Inc., Whippany, NJ 07981

Manufactured in Finland

© 2016, Bayer HealthCare Pharmaceuticals Inc. All rights reserved.