

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICATION
PATIENT MEDICATION INFORMATION**

KYLEENA®

Levonorgestrel-releasing intrauterine system

Read this carefully before you start taking KYLEENA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about KYLEENA.

Serious Warnings and Precautions

- **Hormonal birth control DOES NOT PROTECT against Sexually Transmitted Infections (STIs) including HIV/AIDS. To protect yourself against STIs you can use condoms with KYLEENA.**
- **Cigarette smoking increases the risk of serious side effects on the heart and blood vessels. You should talk to your healthcare professional about the risks of smoking.**
- **KYLEENA may become attached to (embedded) or go through the wall of the uterus. This is called perforation. If you experience severe abdominal or pelvic pain with or without vaginal bleeding contact your healthcare professional immediately.**

What is KYLEENA used for?

KYLEENA is used to prevent pregnancy for up to 5 years.

How does KYLEENA work?

KYLEENA is an intrauterine system (IUS). It is placed in your uterus by your healthcare professional. KYLEENA works by slowly releasing a low amount of a hormone called levonorgestrel directly into the uterus every day. Levonorgestrel is similar to a sex hormone produced naturally by the body. It is also used in many birth control pills (the “Pill”).

KYLEENA may work to prevent pregnancy in several ways including:

- reducing the monthly thickening of the lining of the uterus,
- thickening the mucus in the cervix (this makes it harder for sperm to pass through the cervix), and
- impairing sperm movement and function.

Together, these actions prevent the sperm and egg from coming into contact and work together to prevent pregnancy.

KYLEENA does not contain any estrogen.

In clinical trials, there was less than 1 pregnancy per year for every 100 women using KYLEENA.

KYLEENA is a long acting reversible contraceptive (LARC). LARCs are highly effective in preventing pregnancy, can be used for a long period of time, and are easy to use.

Other Ways to Prevent Pregnancy

Other methods of birth control are available to you. When used properly, other methods of birth control work well enough for many women.

The table below shows the typical pregnancy rates for different methods of birth control. It also shows the pregnancy rate when no birth control is used. The rates show the number of women out of 100 who would become pregnant within the first year of use.

Reported Pregnancies per 100 Women Within the First Year of Use

Hormonal Intrauterine system (IUS)	less than 1
Copper Intrauterine device (IUD)	less than 1
Progesterone Injection	6
Combined hormonal contraceptive (pill, patch or ring)	9
Diaphragm	12
Male condom	18
Female condom	21
Sponge, spermicide	12-28
Withdrawal method	22
Natural family planning	24
No birth control	85

The pregnancy rates listed in the table vary widely. This is because of differences in how carefully and regularly people use each method of birth control. Regular users may have lower pregnancy rates. Others may expect pregnancy rates in the middle ranges. This does not apply to IUSs like KYLEENA because they are placed in the uterus and do not depend on user compliance.

What are the ingredients in KYLEENA?

Medicinal ingredients: levonorgestrel

Non-medicinal ingredients: barium sulphate, copper phthalocyanine, polydimethylsiloxane elastomer, polyethylene, polypropylene, silica colloidal anhydrous, silver.

KYLEENA comes in the following dosage form:

Intrauterine system (IUS): 19.5 mg levonorgestrel

Do not use KYLEENA if you have or have had any of the following conditions:

- allergies to the hormone levonorgestrel, or to any of the other ingredients of KYLEENA or to the components of the container
- are pregnant or think you may be pregnant
- currently have a pelvic infection [pelvic inflammatory disease (PID)] or have had one multiple times
- an untreated infection of your vagina and/or cervix
- an infection of your uterus after delivering a baby
- bleeding from the uterus that has not been explained
- a condition that changes the space inside your uterus, such as large abnormal growths (fibroids)
- abnormalities of the cells in the cervix (your healthcare professional can tell you if you have this)

- a known or suspected tumour that grows in response to progestogen (a hormone). This includes breast cancer
- liver disease or problems
- liver tumour
- an infection of your uterus after an abortion in the past 3 months
- cancer of the uterus or the cervix
- already have an IUS or IUD in your uterus
- tumours related to pregnancy
- an infection of the heart valves or lining of the heart (bacterial endocarditis)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KYLEENA. Talk about any health conditions or problems you may have, including if you:

- are breastfeeding
- have given birth in the last 36 weeks
- have had a stroke, heart attack or any heart problems
- have an abnormality of your heart or if you have any problem with your heart valves
- have a history of blood clots (thrombosis)
- have a history of migraine, dizziness or blurred vision
- have severe headaches
- have or have had liver problems or jaundice (a yellowing of the skin, whites of the eyes and/or nails)
- are diabetic or have a family history of diabetes
- have or someone in your family has high blood pressure or abnormal blood lipid levels (blood fat levels)
- smoke
- have Systemic Lupus Erythematosus
- have a history of emotional problems such as depression
- have a family history of blood clots, heart attacks, or strokes

Other warnings you should know about:

If you see a different healthcare professional, inform him/her that you are using KYLEENA. You should inform your healthcare professional if you are scheduled for Magnetic Resonance Imaging (MRI). KYLEENA can be safely scanned with MRI under most standard conditions.

Tell your healthcare professional if you are scheduled for any lab tests. Certain tests may be affected by hormonal birth control. Also, tell your healthcare professional if you are scheduled for surgery requiring prolonged bed rest.

KYLEENA should be used only under the supervision of your healthcare professional. Visit your healthcare professional 4 to 12 weeks after you have KYLEENA placed. You should have a follow-up visit at least once a year. Your visits may include a blood pressure check, breast exam, pelvic exam (including a Pap smear) and an abdominal exam. Carefully follow all directions given to you. Otherwise, you may become pregnant.

If you and your healthcare professional decide that, for you, the benefits of KYLEENA outweigh the risks, you should be aware of the following:

1. Diabetes

If you have diabetes and use KYLEENA, your blood sugar levels should be watched closely.

2. Infections

In the first 3 weeks after placement of an IUS/IUD, there is an increased risk of a serious pelvic infection called pelvic inflammatory disease (PID). Other known risk factors for PID are having multiple sexual partners, frequent intercourse, sexually transmitted infections (STIs) and young age.

PID can cause serious problems such as difficulty getting pregnant, development of a pregnancy outside the uterus (ectopic pregnancy), or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID may require surgery.

Tell your healthcare professional right away if you have signs of PID. These can include long-lasting or heavy bleeding, unusual vaginal discharge, pain in your lower stomach area, painful sex, chills or fever.

3. Ectopic Pregnancy

While using KYLEENA, the risk of pregnancy is low. However, if you get pregnant while using KYLEENA, it is more likely that the pregnancy will be ectopic. This means that the pregnancy is not in the uterus. Ectopic pregnancy is a serious condition. Tell your healthcare professional immediately if you have lower abdominal pain, especially if you have missed a period and/or have unexpected bleeding. These can be signs of an ectopic pregnancy.

4. Cysts on the Ovary

Cysts (fluid filled sacs) on the ovary commonly occur in women using KYLEENA. These cysts usually disappear within a few months on their own. However, cysts can sometimes cause pain and may need medical attention.

5. Uterine Perforations

Most often during placement, KYLEENA may become attached to (embedded) or go through the wall of the uterus, but this is uncommon. This is called perforation. If this happens, KYLEENA must be removed.

The risk of perforation is higher in women who are breastfeeding when KYLEENA is placed. The risk is also higher when placement takes place up to 36 weeks after a delivery. The risk of perforation may be increased in women with a mis-shaped uterus or a uterus that is fixed and leans backward.

6. Use While Breastfeeding

You can use KYLEENA when you are breastfeeding. The quality and amount of your breast milk is not likely to be affected. Small amounts of the hormone in KYLEENA have been found in the breast milk of women using a different IUS. This does not appear to affect the health of your baby when you start using KYLEENA 6 weeks after delivery.

7. Use in Pregnancy

If you become pregnant with KYLEENA in place, you should have it removed as soon as possible. If it is left in place during pregnancy, the chances of having a miscarriage or early delivery increase. It is not known if KYLEENA can cause long-term effects on the baby if it stays in place during pregnancy. Removing KYLEENA may cause a miscarriage. Talk with your healthcare professional about the benefits and risks of continuing the pregnancy.

8. Use After Pregnancy and Abortion

After childbirth, KYLEENA should be placed only when the uterus has returned to normal size. KYLEENA should not be placed for at least 6 weeks after delivery.

KYLEENA can be placed right after an abortion which took place in the first three months of pregnancy. If an abortion takes place in the second trimester, placement of KYLEENA should be delayed for 6 weeks or until the uterus has returned to normal size.

9. Pregnancy After Stopping KYLEENA

If you wish to become pregnant, ask your healthcare professional to remove KYLEENA. Your usual fertility level should return after removal.

10. Breast Self-Examination

Your healthcare professional should show you how to do breast self-examinations when you are using KYLEENA. If you find any lumps or see any other changes talk to your healthcare professional immediately.

Driving or Using Machines

The effect of KYLEENA on the ability to drive or to use machines has not been studied. Do not drive or use machines until you know how you react to KYLEENA.

How Will KYLEENA Affect My Periods?

KYLEENA may affect your menstrual cycle. 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 vaginal bleeding. Some women have heavy or prolonged bleeding during this time. Contact your healthcare professional if this persists.

Overall, you are likely to have a gradual reduction in the amount and number of days of bleeding each month. Some women eventually find that periods stop altogether.

When KYLEENA is removed, periods soon return to normal.

What if I Stop Having Periods?

Over time, your menstrual period may gradually disappear when using KYLEENA. This is because of the effect of the hormone on the lining of the uterus. The normal monthly thickening of the uterine lining with blood does not happen; therefore, there is little or no bleeding, as happens during a usual menstrual period. It does not necessarily mean you have reached menopause or are pregnant.

If, however, you are having regular menstrual periods and then do not have one for 6 weeks or longer, it is possible that you may be pregnant. You should speak to your healthcare professional.

Tell all healthcare professionals about all the medicines you take. This includes KYLEENA and any other drugs, vitamins, minerals, natural supplements or alternative medicines.

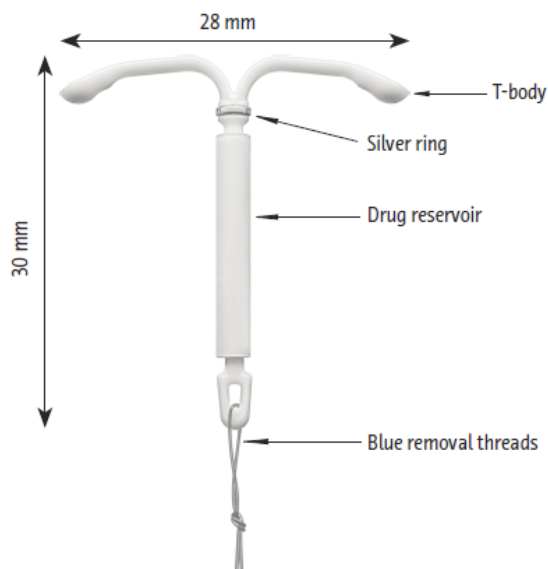
Certain drugs may interact with KYLEENA. They can make it less able to prevent pregnancy. Hormonal birth control may become less reliable if you are taking drugs that affect your liver (such as primidone, barbiturates, phenytoin, carbamazepine, and rifampicin). KYLEENA is not likely to be affected by these drugs. This is because it releases a very small amount of hormone directly inside your uterus. If you are taking other medications, ask your healthcare professional if you need to use an additional method of birth control.

KYLEENA is visible during X-ray exams. KYLEENA also contains a small silver ring that makes it visible by ultrasound.

How to take KYLEENA:

What it looks like:

KYLEENA consists of a small, white, T-shaped body made from soft, flexible plastic. The vertical and horizontal arms of the T-body are about 3 cm long. The vertical arm is surrounded by a narrow, cylindrical shaped drug reservoir that contains levonorgestrel. Two fine blue plastic threads are attached to the tip of the vertical arm. These threads are used for removal of the system. The threads can also be used to check if KYLEENA is in place. In addition, the vertical stem contains a silver ring located close to the horizontal arms, which is visible under ultrasound. KYLEENA is packaged with the EvoInserter (which is used to insert KYLEENA).



How is KYLEENA Placed?

Before KYLEENA is placed, you will have a pelvic exam to determine the position and size of your uterus. You may also have a Pap smear and a breast exam. If necessary, you may also have other tests (ie, for infections including STIs).

Your healthcare professional will insert the thin flexible plastic tube of the insertion device containing KYLEENA into your uterus. Once KYLEENA is in the correct position, your healthcare professional will withdraw the tube and leave KYLEENA in your uterus. Your healthcare professional will trim the removal threads to a suitable length. The procedure takes only a few minutes.

Most women experience either no pain or only mild pain during placement of KYLEENA. Some women may experience some discomfort. You may wish to discuss the need for a painkiller or local anesthetic with your healthcare professional.

Some women may feel dizzy after KYLEENA is placed. This feeling goes away after a short rest. The placement may cause a seizure in patients who have epilepsy. You may also experience some bleeding during or just after placement. After placement you may feel some cramp-like menstrual pain; however, this usually stops within a few days.

It is not likely, but KYLEENA may go through the wall of the uterus during placement and come to rest outside the uterus. If this happens KYLEENA must be removed.

When Should KYLEENA be Placed?

KYLEENA should be inserted within 7 days of the start of your period.

When replacing an existing KYLEENA for a new one, it is not necessary to wait for your period. A new KYLEENA can be placed at any time of the cycle.

How Quickly Does KYLEENA Start to Work?

KYLEENA starts to work right away if it is placed within 7 days of the start of your period. It is best to wait 24-48 hours before having intercourse in case of discomfort.

How Often Should I Have KYLEENA Checked?

You should have KYLEENA checked about 4 to 12 weeks after it is inserted, again at 12 months and then once a year until it is removed. KYLEENA can stay in place for up to 5 years before it must be removed. You should receive a Patient Reminder Card from your healthcare professional after the placement of KYLEENA. Keep this card until KYLEENA is removed and bring it with you to every medical appointment.

How Can I Check if KYLEENA is in Place?

After each menstrual period or about once a month, you should check by feeling if the threads are still in place. Your healthcare professional will show you how to do this. Do not pull on the threads as you may accidentally pull KYLEENA out.

If you cannot feel the threads, this may mean that KYLEENA has fallen out (expulsion) or gone through the uterus (perforation). See your healthcare professional and in the meantime, use another method of birth control that does not include hormones. You should also see your healthcare professional if you can feel the lower end of KYLEENA itself.

Will KYLEENA be felt during Sexual Intercourse?

You and your partner should not be able to feel KYLEENA during intercourse. If you can feel KYLEENA or if you feel any pain, avoid having sex until your healthcare professional has checked if KYLEENA is still in the correct position.

The removal threads may be felt by your partner during intercourse.

Can Tampons be Used?

Use of sanitary pads is recommended. If tampons are used, you should change them carefully so as not to pull the threads of KYLEENA.

Can KYLEENA Fall Out?

Although unlikely, KYLEENA may fall out on its own. This is called expulsion. If this happens, you are not protected against pregnancy. An unusual increase in the amount of bleeding during your period might be a sign that this has happened. If you think KYLEENA has fallen out, use a non-hormonal method of birth control and talk to your healthcare professional.

Removal of KYLEENA

KYLEENA should not be left in place for more than 5 years. You should see your healthcare professional when you want to have KYLEENA taken out. Removal of KYLEENA is usually very easy.

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 professional 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.

If you wish to continue using KYLEENA after 5 years, your healthcare professional can insert a new system immediately after removing the old system. If the same KYLEENA system has been left in place for longer than 5 years, you may become pregnant. Pregnancy should be ruled out before insertion of a new system.

What are possible side effects from using KYLEENA?

These are not all the possible side effects you may feel when taking KYLEENA. If you experience any side effects not listed here, contact your healthcare professional. Please also see the box called “Serious Warnings and Precautions.”

Side effects with KYLEENA are more common during the first months of use; they gradually decrease over time. Differences in your menstrual bleeding are the most common side effects of KYLEENA during the first months after the system is inserted, but these effects should decrease over time.

Very common side effects (may affect more than 1 in 10 women):

- acne/oily skin

Common side effects (may affect up to 1 in 10 women):

- nausea
- hair loss
- infection of the ovaries, fallopian tubes or uterus
- painful menstruation
- breast pain/discomfort
- discharge from the vagina

Uncommon side effects (may affect up to 1 in 100 women):

- excess hair on the face, chest, stomach or legs

Women using a different IUS have reported cases of the following events. Talk with your healthcare professional if any of these occur:

- blood clots in the lungs (symptoms may include sharp pain in the chest, shortness of breath, coughing up blood), blood clot in the leg (symptoms may include pain, warmth, redness and swelling in the leg) or blood clot in the brain (stroke) (symptoms may include sudden severe headache, vomiting, dizziness, fainting, problems with vision or speech, weakness or numbness in the face, arm or leg)
- breakage of the IUS
- allergic reaction (symptoms may include rash, hives, or sudden swelling of the face, lips, cheeks, tongue or throat)
- increased blood pressure

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM			
Symptom/ effect	Talk with your Healthcare Professional		Get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Vaginal bleeding changes: increased or decreased menstrual bleeding, spotting, infrequent periods or absence of bleeding	✓		
Vaginal Infection (inflammation of the vagina or surrounding area): itching, or unusual or increased discharge from the vagina		✓	
Headache	✓		
Abdominal pain/ pelvic pain	✓		
Cysts on the ovaries: Pelvic pain, painful intercourse, abdominal bloating or swelling, pain during bowel movements. (Cysts usually disappear on their own within a few months and may not show symptoms. Serious cysts are uncommon.)	✓		
COMMON			
Expulsion (KYLEENA has fallen out): An unusual increase in the amount of bleeding during your period		✓	
Migraine	✓		
Depressed Mood/Depression: Sad mood that won't go away. If you have a history of depression, your depression may become worse		✓	
UNCOMMON			
Pelvic Infection: Constant pain in the lower stomach area, together with fever or unusual discharge from the vagina		✓	
Intrauterine pregnancy, miscarriage, or ectopic pregnancy: Constant pain in the lower stomach area, together with nausea or breast tenderness and/or vaginal bleeding		✓	

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/ effect	Talk with your Healthcare Professional		Get immediate medical help
	Only if severe	In all cases	
Perforation of the uterus [attached to (embedded) or gone through the wall of the uterus]: Severe lower abdominal pain which may be together with bleeding		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect \(www.healthcanada.gc.ca/medeffect\)](http://www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect).

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage

Store at controlled room temperature (between 15°C and 30°C).

Keep out of reach and sight of children.

If you want more information about KYLEENA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professional and includes this Patient Medication Information by visiting the Health Canada website (www.healthcanada.gc.ca); the manufacturer's website <http://www.bayer.ca> or by contacting Bayer at 1-800-265-7382.

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