KYLEENA™
INFORMATION FOR USERS



Kyleena™

19,5 MG LEVONORGESTREL
INTRAUTERINE DELIVERY SYSTEM

5 years. Low dose.

Table of Contents

Welcome to Kyleena™ 4

What is Kyleena™? 5

How does Kyleena™ work? 6

What you need to know about the insertion

- How is Kyleena™ inserted, and how long does it take 7
- When should Kyleena™ be inserted? 7
- Does Kyleena™ cause a risk of perforation? 7
- Does Kyleena™ need to be checked after it has been inserted? 8
- What are the threads attached to Kyleena™? 8

What to expect: my first week with Kyleena™

- How will Kyleena™ affect my period? 10
- Can I still use tampons? 11
- Will Kyleena™ affect my sexual intercourse? ... 11

What else do I need to know about Kyleena™?

- How will Kyleena™ affect my skin? 13
- Does Kyleena™ have an effect on my ovaries? 13
- How will Kyleena™ affect my fertility?..... 13
- Can I suffer from mood changes? 13
- Is there a risk of ectopic pregnancy with Kyleena™? 14
- Is there a risk of infection with Kyleena™? 14
- Does Kyleena™ protect against sexually transmitted infections (STIs)?. 15
- Can Kyleena™ fall out? 15
- What happens after 5 years? How is Kyleena™ removed?..... 15
- What happens if I decide I want a baby?..... 15
- What are the side effects associated with Kyleena™? 16

Where can I get more information?..... 17

How does the IUS reminder service work? 18

- What do I need to do? 18
- The reminder service 18

How effective are intrauterine systems in comparison to other methods?..... 20

Kyleena™ menstrual diary 22

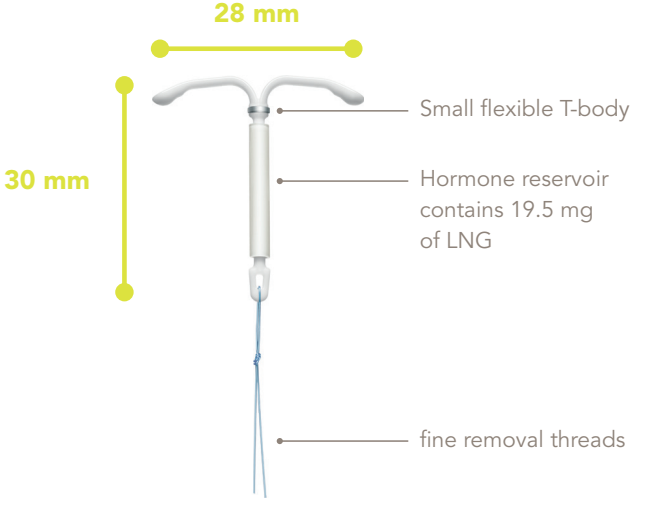


Welcome to Kyleena™

Your healthcare professional (HCP) has talked to you about the Kyleena™ intrauterine system (IUS) and prescribed Kyleena™ for you as contraception. This brochure will provide you with answers to the most frequently asked questions about contraception with Kyleena™.

What is Kyleena™?[1,2]

Kyleena™ is used for the prevention of pregnancy (contraception) for up to 5 years. Kyleena™ is a T-shaped intrauterine delivery system (IUS), which after placement inside the womb, slowly releases a small amount of the hormone levonorgestrel (LNG). The T-shaped frame of Kyleena™ is just 28 x 30 mm. There are fine threads attached which are used by your doctor to remove Kyleena™.



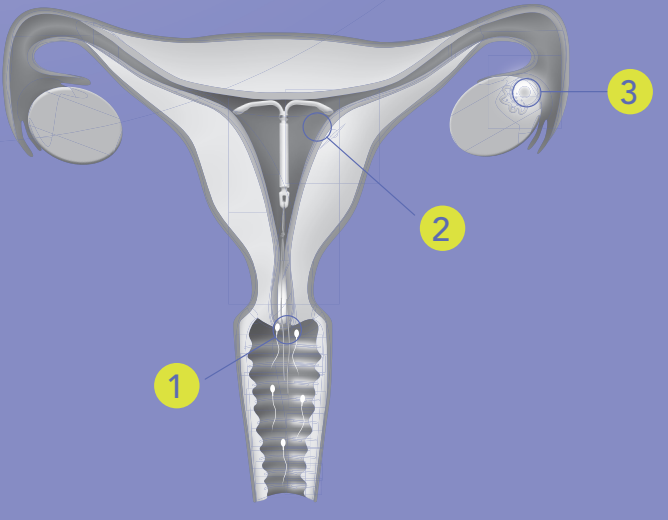
Have you held a Kyleena™ demo in your hand? Ask your healthcare professional to show you how small and flexible it is.

How does Kyleena™ work?[1]

Kyleena™ works by thickening the cervical mucus which inhibits passage of the sperm through the cervical canal. This prevents the sperm and egg from coming into contact and prevents fertilization. Kyleena™ also reduces the monthly growth of the lining of the womb.

Important aspects of Kyleena™:

- Releases only a low dose of hormone
- Does not contain estrogen
- Does not affect the normal function of your ovaries



1. Kyleena™ works by thickening the cervical mucus which inhibits passage of the sperm through the cervical canal. This prevents the sperm and egg from coming into contact and prevents fertilization.

2. Kyleena™ also reduces the monthly growth of the lining of the womb.

3. Since these effects are mainly local, ovulation (release of the egg) usually continues while using Kyleena™.

What you need to know about the insertion

How is Kyleena™ inserted, and how long does it take?[1]

The insertion procedure should take no longer than a few minutes. Your healthcare professional will first perform a pelvic examination. A thin flexible tube containing Kyleena™ will then be inserted into your womb. Once Kyleena™ is in the correct position, your healthcare professional will withdraw the insertion tube leaving Kyleena™ in place. You may experience some pain and/or dizziness during placement. If you would like pain relief before Kyleena™ is inserted, please speak to your healthcare professional about preventive pain-relieving treatment.

After insertion, you may feel some pain similar to menstrual cramps. However, this usually disappears within a few days. If you experience severe pain or heavy bleeding after Kyleena™ is inserted or if pain/bleeding persists for more than a few weeks, please make an appointment to see your healthcare professional.

When should Kyleena™ be inserted?[1]

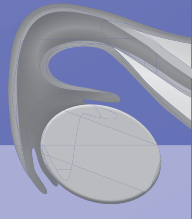
Kyleena™ should be placed within 7 days from the start of your monthly period. You will be protected from pregnancy immediately. When replacing an intrauterine system with a new one, it is not necessary to wait with your period.

Does Kyleena™ cause a risk of perforation?[1]

Perforation or penetration of the uterine corpus or cervix by Kyleena™ may occur, most often during insertion, although the perforation may not be detected until some time later. If Kyleena™ becomes lodged outside the cavity of the womb, it will not be effective in preventing pregnancy. You may need surgery to have Kyleena™ removed. The risk of perforation is increased in breast-feeding women, and in women who have insertion up to 36 weeks after birth, and may be increased in women with a uterus leaning backwards (fixed retroverted uterus).

Does Kyleena™ need to be checked after it has been inserted?[1]

You should have your Kyleena™ checked 4–12 weeks after placement, and thereafter regularly, at least once a year. Your healthcare professional may determine how often and what kinds of check-ups are required in your particular case.



Kyleena™ in the womb

What are the threads attached to Kyleena™?[1]

The 2 threads allow your healthcare professional to remove Kyleena™. Your healthcare professional may show you how to check that the threads are present. Being able to feel the threads can reassure you that Kyleena™ is still in place and providing effective contraception. If you have any additional questions about the threads, talk to your healthcare professional.


threads



What to expect: my first weeks with Kyleena™

How will Kyleena™ affect my period?[1]

Kyleena™ is likely to affect your menstrual cycle. It can change your menstrual periods so that you experience spotting (a small amount of bleeding), shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.



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.

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

- This is due to the way Kyleena™ works: the hormone levonorgestrel reduces the monthly thickening of the lining of the womb to prevent pregnancy and therefore, there is no tissue to shed away as a menstrual period. There is no indication that an absence of monthly periods will affect your future fertility. Your own hormone levels usually remain normal.
- Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms of pregnancy you should see your healthcare professional for an examination and have a pregnancy test.
- If you have not had a period for 6 weeks and are concerned, then consider having a pregnancy test. If this is negative, there is no need to carry out another test unless you have other signs of pregnancy.

A menstrual diary is included with this brochure to help you keep track of changes in your monthly cycle.

When Kyleena™ is removed, your period should soon return to normal.

Can I still use tampons?

You can continue to use tampons during your period, but please be careful when changing them. Do not accidently pull the threads of Kyleena™.

Will Kyleena™ affect my sexual intercourse?

You and your partner should not feel Kyleena™ during intercourse. Kyleena™ is placed in the womb, not in the vagina.



What else do I need to know about Kyleena™?

How will Kyleena™ affect my skin?[1]

The development of acne is influenced by both hormonal and non-hormonal factors.[3] As with other levonorgestrel-containing hormonal contraceptives, some women may experience greasy skin or acne when using Kyleena™. If you have previously used estrogen-containing hormonal birth control method and experienced a positive effect on your skin, you may notice a change when switching to Kyleena™ as Kyleena™ is an estrogen free birth control method.

Does Kyleena™ have an effect on my ovaries?[1]

Although the contraceptive efficacy of Kyleena™ is mainly due to its local effect in the womb, an ovarian cyst may sometimes develop. In most cases there are no symptoms.

While using Kyleena™, your healthcare professional might detect such a cyst when performing a routine vaginal ultrasound. Ovarian cysts are transient and mean no harm in the vast majority of cases. Rarely it may require medical attention, or even more rarely surgery.

How will Kyleena™ affect my fertility?[1]

Kyleena™ is completely reversible. That means that your natural level of fertility will return after Kyleena™ is removed.

Kyleena™ can be removed at any time. This means, if you are planning to get pregnant, Kyleena™ can be removed by your healthcare professional in one short visit. Once Kyleena™ is removed, you can try to get pregnant right away.

Can I suffer from mood changes?[1]

Women sensitive to levonorgestrel side effects may experience that Kyleena™ has an effect on their mood (depressed mood/ depression).

If you suffer with these symptoms, please discuss with your healthcare professional whether they may resolve on their own or if Kyleena™ should be removed.

What else do I need to know about Kyleena™ (cont.)?

Is there a risk of ectopic pregnancy with Kyleena™?[1]

It is unlikely to become pregnant while using Kyleena™. However, if you become pregnant while using Kyleena™, the risk that the pregnancy could develop outside the womb (an extrauterine or ectopic pregnancy) is increased. Women who have already had an extrauterine pregnancy, surgery on the fallopian tubes, or a pelvic infection carry a higher risk for this type of pregnancy. An extrauterine pregnancy is a serious condition which calls for immediate medical attention and may impact future fertility. You should tell your healthcare professional if you experience lower abdominal pain, especially if you have missed a period (and were previously having regular periods) and/or have unexpected bleeding, and/or normal signs of pregnancy as these can be indicators of an ectopic pregnancy.

Is there a risk of infection with Kyleena™?[1]

Kyleena™, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease. Condoms are recommended to prevent sexually transmitted diseases.

The Kyleena™ inserter and Kyleena™ itself are sterile and the risk of infection is comparable to that in non-IUS users and is strongly associated with risk factors, such as multiple sexual partners, sexually transmitted infections, and prior history of i.e. Pelvic Inflammatory Disease (PID).

Despite this, there is an increased risk of pelvic infection (infections in the lining of the womb or the fallopian tubes) at the time of placement and during the first 3 weeks after the placement.

Your healthcare professional will perform a full examination prior to the insertion to ensure that there are no existing infections.

Pelvic infections must be treated promptly.

Does Kyleena™ protect against sexually transmitted infections (STIs)?[1]

No, Kyleena™ does not protect against STIs, including HIV/AIDS. For protection against STIs, is it advisable to use a condom.

Can Kyleena™ fall out?[1]

While unlikely, it is possible that Kyleena™ could partially or completely come out of place. If this happens, you will not be protected against pregnancy. An unusual increase in the amount of bleeding during your period or pain may be a sign that this has happened. Feeling the threads can reassure you that Kyleena™ is still in place and providing effective contraception.

If you think that Kyleena™ has come out of place, use a non-hormonal method of contraceptive (such as condoms) until you see your healthcare professional.

What happens after 5 years?[1] How is Kyleena™ removed?

Kyleena™ should be removed no later than the end of the fifth year of use. Kyleena™ can be easily removed at any time by your healthcare professional, after which you will return to your natural level of fertility.

Some women feel dizzy during or after Kyleena™ is removed. You may experience some pain and bleeding during removal of Kyleena™.

What happens if I decide I want a baby?[1]

Kyleena™ can be removed at any time and your normal level of fertility should return soon after it has been removed.

What else do I need to know about Kyleena™ (cont.)?

What are the side effects associated with Kyleena™?[1]

As your body adapts to Kyleena™, some effects may occur to your body, as explained before. Below is a list of potential side effects. Please consult your healthcare professional, if you have any questions.

Very common:
may affect more than 1 in 10 people

- Headache
- Abdominal/pelvic pain
- Acne/seborrhea ("greasy skin")
- Bleeding changes including increased and decreased menstrual bleeding, spotting, oligomenorrhea (infrequent periods), and amenorrhea (absence of bleeding)
- Ovarian cyst
- Vulvovaginitis (inflammation of the external genital organs or vagina)

Common:
may affect up to 1 in 10 people

- Depressed mood/depression
- Migraine
- Nausea (feeling sick)
- Alopecia (hair loss)
- Upper genital tract infection
- Dysmenorrhea (painful menstruation)
- Breast pain/discomfort
- Device expulsion (complete and partial)
- Genital discharge

Uncommon:
may affect up to 1 in 100 people

- Hirsutism (excessive body hair)

Rare:
may affect up to 1 in 1,000 people

- Uterine perforation*

If you wish to continue using Kyleena™ after 5 years, your healthcare professional can remove Kyleena™ and insert a new one.

Where can I get more information?

This brochure does not replace the patient information. If you have additional questions, please ask your healthcare professional for more information.

*The perforation risk is higher (up to 1 in 100 people) in women who are breastfeeding at the time of IUS insertion, and when the IUS is inserted up to 36 weeks after a delivery.

How does the IUS reminder service work?

What do I need to do?

This program offers a service which reminds you that your Intra Uterine System (IUS) i.e, your Kyleena™ needs to be replaced. Once you have registered, we will send you an SMS or email 3 months before the 5 years mark from the date of your insertion of your Kyleena™ reminding you that your Kyleena™, is due to be replaced. Should your contact details, that used during registration, have changed during this 5 year period, you can update it by sending an email to za_psp@bayer.com.

3 Months prior to your replacement date, an SMS or email will be sent to you in order to enable you to schedule an appointment with your healthcare practitioner for an replacement.

Your participation in the program is voluntary and your personal information is protected by the Privacy Statements contained in the consent you provide.

All information will be treated as strictly confidential. You may withdraw from the program at any time during the 5 year period. Should you choose to be part of the IUS Patient Reminder Program, kindly complete the consent form by clicking on www.bayer.co.za/molr and register. Please note you may also register using a hard copy version of the registration form, which is available from your attending healthcare professional.

Reminder service:

1. Log on to the website
2. Fill in your details as well as insertion date
3. Ensure that you read and understand ALL the terms and conditions
4. Provide your healthcare professionals' information
5. Click on the accept terms and conditions
6. Click send

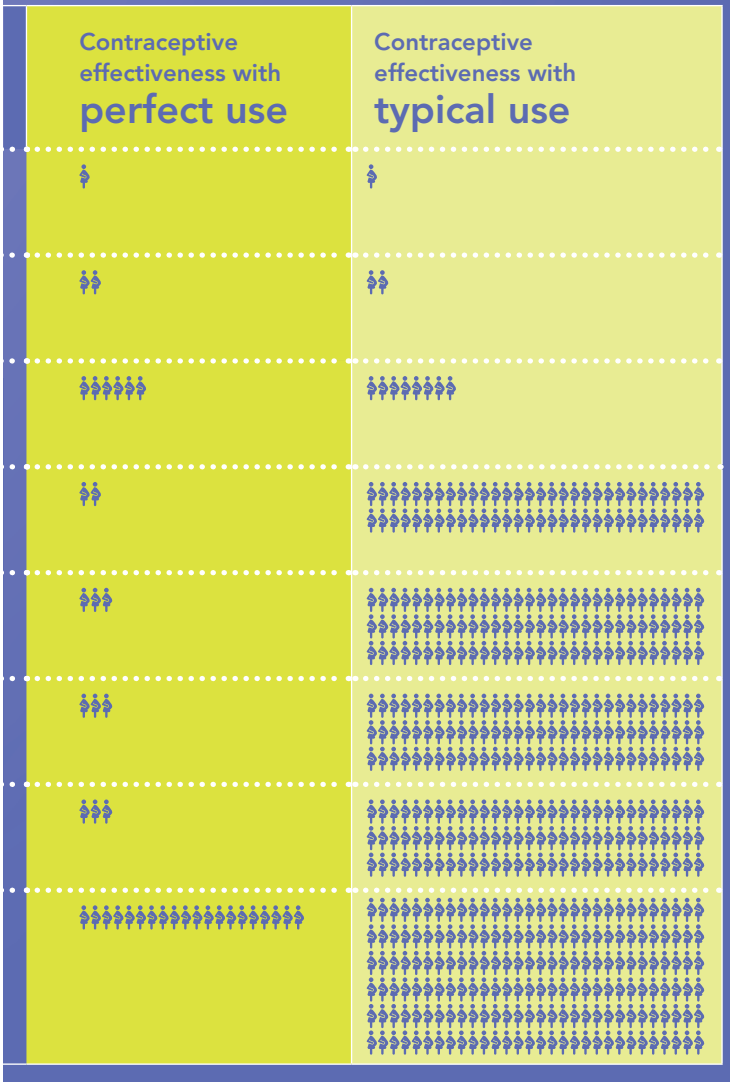


How effective are intrauterine systems in comparison to other methods?[3,4]

Product	
Implant	
Hormonal intrauterine system (IUS)	
Copper spiral or chain (IUD)	
3-monthly contraceptive injection	
Pill	
Birth control patch	
Birth control ring	
Condom*	

* Male condom

PREGNANCIES FOR EVERY 1,000 WOMEN DURING FIRST YEAR OF USE



The efficacy of Kyleena™ is independent of daily routine

Kyleena™ menstrual diary

You can use this menstrual diary to keep track of changes to your cycle, including spotting or bleeding that may occur over the next few months. Record your menstrual blood flow or any bleeding that occurs between periods by marking in the appropriate square (day) of the calendar, using the following guide:

No Bleeding: Leave blank

Spotting: Mark a dot

Normal Flow: Mark an X

Heavy Flow: Fill in the box

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																															
Month 2*																															
Month 3																															
Month 4																															
Month 5																															
Month 6																															

*You should have a check-up within 4–6 weeks after Kyleena™ is inserted

Patient name:

.....

Date of insertion:

.....

Healthcare professional name:

.....

Healthcare professional telephone number:

.....

1. Bayer. Kyleena™ Package Insert South Africa, 2017. **2.** Gemzell-Danielsson K et al PLoS One 2015;10(9):e0135309. **3.** NHS choices. Acne – causes. Accessed at: http://www.nhs.uk/Conditions/Acne/Pages/Causes.aspx. **4.** WHO. Medical Eligibility Criteria for Contraceptive Use: A WHO Family Planning Cornerstone. 5th edition Geneva: World Health Organization. 2015. **5.** Trussell J. Contraception 2011;83:397–404.

S4 Kyleena™ Levonorgestrel intrauterine system. Each sterile intrauterine system contains levonorgestrel 19.5mg, 12 µg/24hrs. RSA Reg No: A 47/32.9/0037.

For full prescribing information, refer to the package insert approved by the medicines regulatory authority.

Bayer (Pty) Ltd Reg. No. 1968/011192/07 27 Wrench Road Isando 1609
South Africa Tel: 011 921 5000. L.ZA.MKT.06.2018.2656

www.bayer.co.za

BAYER

Kyleena™
19,5 MG LEVONORGESTREL
INTRAUTERINE DELIVERY SYSTEM

5 years. Low dose.