

KYLEENA®

INFORMATION FOR USERS

This booklet is intended for patients
prescribed Kyleena.

 **kyleena®**
19.5 MG INTRAUTERINE DELIVERY SYSTEM
LEVONORGESTREL

5 years. Low dose.*



Table of Contents

Welcome to Kyleena	4
---------------------------------	---

What is Kyleena?	5
-------------------------------	---

How does Kyleena work?	6
-------------------------------------	---

Can any woman use Kyleena?	6
---	---

What you need to know about the insertion

- How is Kyleena inserted, and how long does it take7
- When should Kyleena be inserted?7
- Can Kyleena cause 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 weeks with Kyleena

How will Kyleena affect my period?.....	10
Can I use tampons or menstrual cups?.....	11
Will Kyleena interfere with 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
- Does Kyleena cause mood changes?14

• Magnetic resonance imaging (MRI)	14
• Is there a risk of ectopic pregnancy with Kyleena?.....	14
• Is there a risk of infection with Kyleena?.....	15
• Does Kyleena protect against sexually transmitted infections (STIs)?	15
• Can Kyleena fall out?	16
• What happens after 5 years? How is Kyleena removed?	16
• What happens if I decide I want a baby?	16
• What are the side effects associated with Kyleena?.....	18
Where can I get more information?	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. You can also refer to the Consumer Medicine Information leaflet for further information about Kyleena, available via QR code: Always speak to your doctor if you are unsure or have any other questions.



What is Kyleena?^{1,3}

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 uterus, 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.

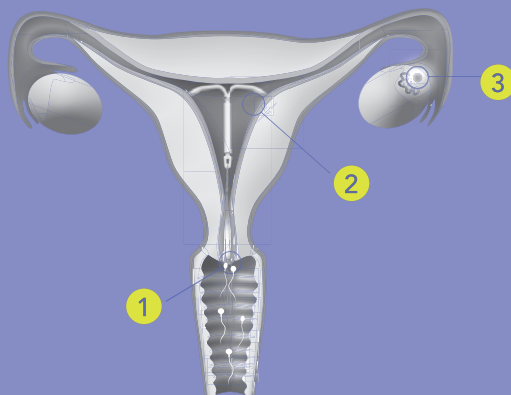
How does Kyleena work?^{1,3,4}

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 fertilisation. Kyleena also reduces the monthly growth of the lining of the uterus. Kyleena is one of the most effective and reliable methods of contraception available. Studies have shown that of 1,000 women who use Kyleena for 1 year, no more than 2 are likely to become pregnant. This is similar to female sterilisation. Once Kyleena is properly fitted, and provided it stays in position, it is effective for up to 5 years of continuous use and the reliability remains over 98.5% over this time.

Important aspects of Kyleena:

- Releases a low dose of the hormone levonorgestrel
- Does not contain estrogen

- 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 fertilisation. The normal sperm function is also inhibited inside the uterus.
- 2 Kyleena also reduces the monthly growth of the lining of the uterus.
- 3 Since these effects are mainly local, ovulation (release of the egg) usually continues while using Kyleena.



Can any woman use Kyleena?¹

As with all methods of contraception or hormone treatments, Kyleena will not be suitable for everyone. For example, if you are pregnant or suspect you may be pregnant, you cannot use Kyleena. If you are unsure whether Kyleena is suitable for you, discuss this with your doctor. You can also refer to the Consumer Medicine Information leaflet for further information on Kyleena, available by calling 1800 008 757 or via QR code:



What you need to know about the insertion

How is Kyleena inserted, and how long does it take?^{1,3,5}

Preparations for the insertion usually take about 5 to 10 minutes, and the actual insertion of Kyleena will usually take only a few minutes. Your healthcare professional will first perform a pelvic examination. A thin flexible tube containing Kyleena will then be inserted into your uterus. 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.

Your doctor will also have told you to expect some spotting or light bleeding at first which will typically settle during the first 3–6 months of use.¹ Panty liners should be all that is required for protection during the first week after fitting. Afterwards you may feel some cramping, similar to period pain, and occasionally some dizziness may also occur. These symptoms usually disappear after a few hours but if they persist or you are concerned, please contact your doctor or their practice nurse.

It is also recommended that you do not insert anything into your vagina for 48 hours after Kyleena is fitted to minimise your risk of infection. This includes avoiding sexual intercourse, tampons, menstrual cups, swimming and baths.⁵

When should Kyleena be inserted?^{1,3}

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 for your period.

Can Kyleena cause perforation?^{1,3}

There is a small risk (around 2 in 1,000) that Kyleena may perforate or be pushed through the wall of your uterus. This occurs most often during placement of Kyleena, although it may not be detected until sometime later. The risk of perforation increases in breastfeeding women and when Kyleena is inserted after giving birth. The risk may also be increased in women with a fixed retroverted uterus (tilted uterus). If you experience excessive pain or bleeding during or after insertion, or at any time during the use of Kyleena, tell your doctor immediately.

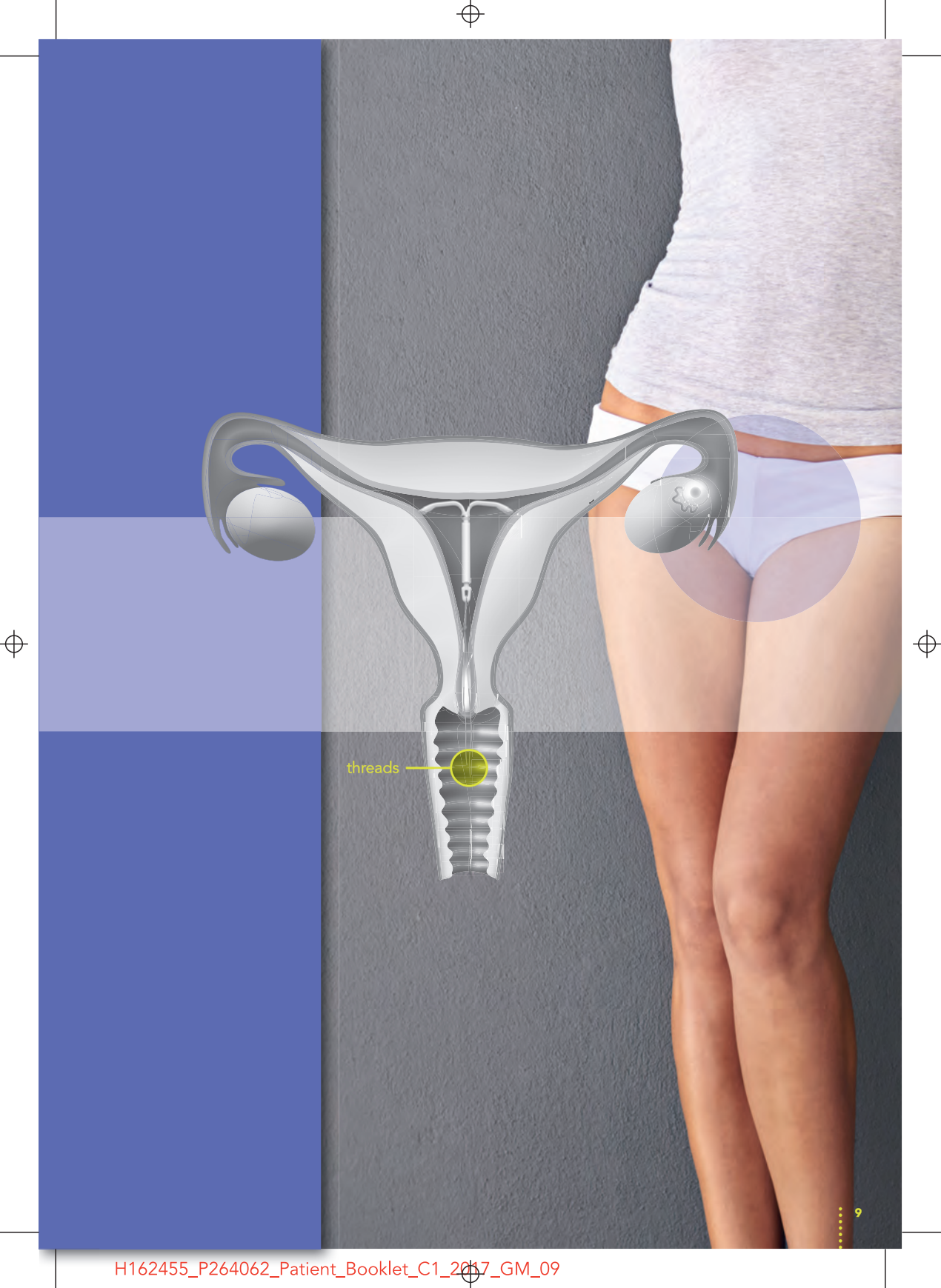
Does Kyleena need to be checked after it has been inserted?^{1,3}

You should have your Kyleena checked 4–6 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 uterus

What are the threads attached to Kyleena?^{1,3}

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. Do not pull on the threads as you may accidentally pull your Kyleena out. If you can't feel the threads, please see your doctor to make sure your Kyleena is still in position. 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?^{1,3}

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. Tell your doctor if bleeding remains heavy or irregular.

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 uterus 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.

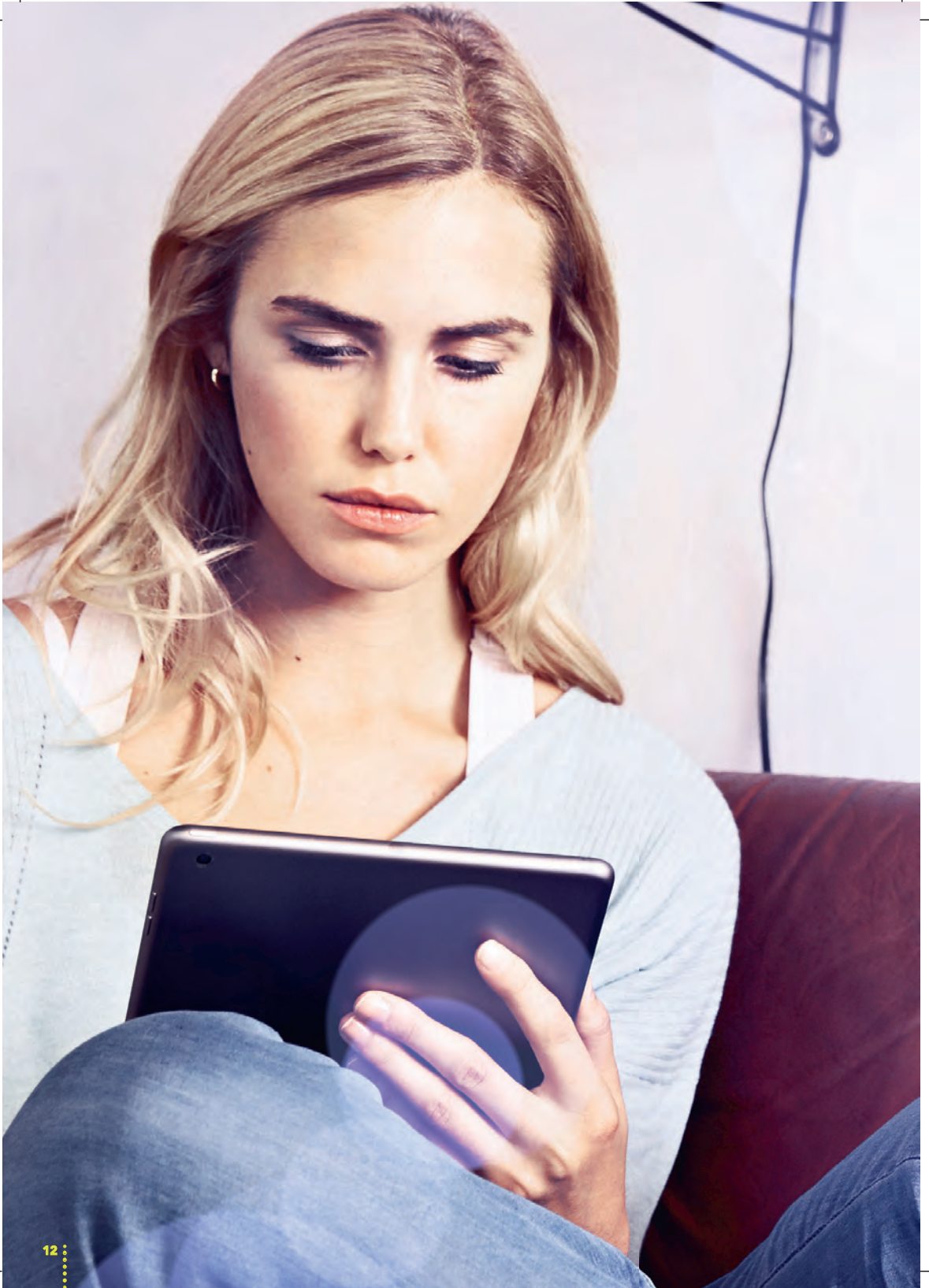
When Kyleena is removed, your period should soon return to normal.

Can I use tampons or menstrual cups?⁵

Nothing should be inserted into the vagina for 48 hours following insertion of Kyleena, including tampons and menstrual cups. After this time, tampons and menstrual cups can be used. Tampons will not change the position or effectiveness of Kyleena. However, while it is unlikely to happen, care must be taken when changing them so the threads of Kyleena are not pulled and Kyleena accidentally removed. While there is no evidence that the use of menstrual cups is associated with a risk of Kyleena being expelled or falling out, caution may be warranted in the first few weeks after insertion of Kyleena.

Will Kyleena interfere with sexual intercourse?^{1,3,5}

If Kyleena is fitted within the first seven days of the menstrual cycle, it will protect against pregnancy as soon as it is inserted. However, it is best to wait about 48 hours before having sexual intercourse. Neither you or your partner should feel your Kyleena during intercourse. If you do, intercourse should be avoided or another contraceptive should be used (e.g. condoms) until your doctor has checked that your Kyleena is still in the correct position. Occasionally it may be possible for your partner to feel the ends of the threads. If this causes concern or discomfort, the length of the threads can be adjusted for you.



What else do I need to know about Kyleena?

How will Kyleena affect my skin?^{1,3}

The development of acne is influenced by both hormonal and non-hormonal factors.² 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?^{1,3}

Although the hormonal effect of Kyleena is mainly localised inside the uterus, a small amount of the hormone is absorbed into your blood circulation. Most women will still ovulate because the amount absorbed into the blood stream is not enough to suppress ovulation. As the level of hormone in the circulation is very low, the hormonal side effects are generally mild in nature and are more commonly reported in the first few weeks and months of use. If they do occur, they usually settle after the first few months. Ovarian cysts or enlarged groups of cells (follicles) have been reported with the use of Kyleena. You may not experience any symptoms with ovarian cysts or follicles, but in some cases they may cause pelvic pain or pain during intercourse. In most cases, the follicles resolve spontaneously.

How will Kyleena affect my fertility?^{1,3}

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.

What else do I need to know about Kyleena?

Does Kyleena cause mood changes?³

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 these may resolve on their own or if Kyleena should be removed.

Magnetic resonance imaging (MRI)³

The vertical stem of the IUS contains a silver ring. Before you have an MRI, tell any other doctors who treat you that you are using Kyleena, an intrauterine system. Kyleena can be scanned with MRI only under specific conditions.

Is there a risk of ectopic pregnancy with Kyleena?³

It is very rare to become pregnant while using Kyleena. However, if you become pregnant while using Kyleena, the risk that the pregnancy could develop outside the uterus (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.** See your doctor without delay if you notice your menstrual periods cease and then you start having persistent bleeding or pain, if you have vague or very bad pain in your lower abdomen, or if you have normal signs of pregnancy but you also have bleeding and feel dizzy.



Is there a risk of infection with Kyleena?^{1,3,5}

Kyleena itself will not increase your risk of pelvic infection. However, the insertion procedure itself may result in a slightly increased risk of pelvic infection during the first month after Kyleena is fitted.

You have an increased risk of pelvic infections if you have multiple sexual partners, acquire a sexually transmitted infection (STI) or have a history of pelvic inflammatory disease. When having sex with anybody who is not a long-term partner, a condom should be used to minimise the risk of infection.

It is also recommended that you do not insert anything into your vagina for 48 hours after Kyleena is fitted to minimise your risk of infection. This includes avoiding sexual intercourse, tampons, menstrual cups, swimming and baths.

Tell your doctor without delay if you have persistent lower abdominal pain, fever, pain during sexual intercourse or abnormal bleeding – these may be signs of infection and should be treated promptly.

Does Kyleena protect against sexually transmitted infections (STIs)?³

Kyleena does not protect against HIV infection (AIDS) and other STIs. Additional methods should be used (i.e. condoms) to prevent transmission of STIs.



Can Kyleena fall out?³

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 Kyleena comes out either partially or completely there may be some signs to alert you, like an unusual increase in bleeding, possibly some pain, you or your partner may be able to feel the lower end of the system itself, the removal threads may seem longer, or you may not be able to feel them at all. It is also rare but possible for this to happen without you noticing during your menstrual period.

Each month, you can check Kyleena is in place by feeling for the two thin threads attached to the lower end of Kyleena. Your doctor will show you how to do this.

Do not pull on the threads because you may accidentally pull out your Kyleena.

If Kyleena comes out partially or completely, you will not be protected against pregnancy. You should avoid intercourse or use another form of contraception (e.g. condoms) and see your doctor as soon as you can.

What happens after 5 years?¹ How is Kyleena removed?³

Kyleena should be removed no later than the end of the fifth year of use. Kyleena can be 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?^{1,3}

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?

What are the side effects associated with Kyleena?³

All medicines can have side effects. Some people may experience side effects while using Kyleena, while others may not experience any. Side effects are most common during the first months after Kyleena is placed and decrease as time goes on. Do not be alarmed by the following side effects, you may not experience any of them.

Some possible side effects of Kyleena may include:

- pain, bleeding, dizziness and fainting during placement or removal of Kyleena
- headache
- abdominal/pelvic pain
- acne, oily skin
- bleeding changes including increased or decreased menstrual bleeding, spotting, infrequent or light periods, absence of bleeding
- itching, redness and/or swelling of the vagina
- depressed mood/depression
- migraine
- nausea
- hair loss or excessive hairiness
- vaginal infections and discharge
- menstrual pain
- breast pain or discomfort
- expulsion of the IUS

Tell your doctor or pharmacist if you notice any of the above side effects, particularly if they worry you.

For more information about possible side effects, refer to the Consumer Medicine Information leaflet available by calling 1800 008 757 or via the QR code:





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 Consumer Medicine Information. Always speak to your doctor if you are unsure or have any other questions. You can call 1800 008 757 or refer to the Consumer Medicine Information leaflet for further information about Kyleena, available via QR code:







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 with your doctor within 4-6 weeks after Kyleena is inserted and yearly thereafter



Patient name:

.....

Date of insertion:

.....

Healthcare professional name:

.....

Healthcare professional telephone number:

.....

1. Kyleena Product Information, May 2018. 2. NHS choices. Acne – causes. Accessed at: <http://www.nhs.uk/Conditions/Acne/Pages/Causes.aspx>. Date accessed: 10 Feb 2020. 3. Kyleena Consumer Medicines Information, May 2018. 4. Trussell J. Contraception 2011;83:397–404. 5. Family Planning New South Wales, Family Planning Victoria and True Relationships and Reproductive Health. Contraception: An Australian Clinical Practice Handbook, 4th Edition. Ashfield, NSW, 2016.

Bayer Australia Limited, ABN 22 000 138 714,
875 Pacific Highway, Pymble NSW 2073.

Kyleena® is a Registered Trademark of the Bayer Group, Germany.

PP-KYL-AU-0004-2 Prepared May 2023