



KYLEENA™

INFORMATION FOR USERS



This brochure is intended for users who have been prescribed Kyleena

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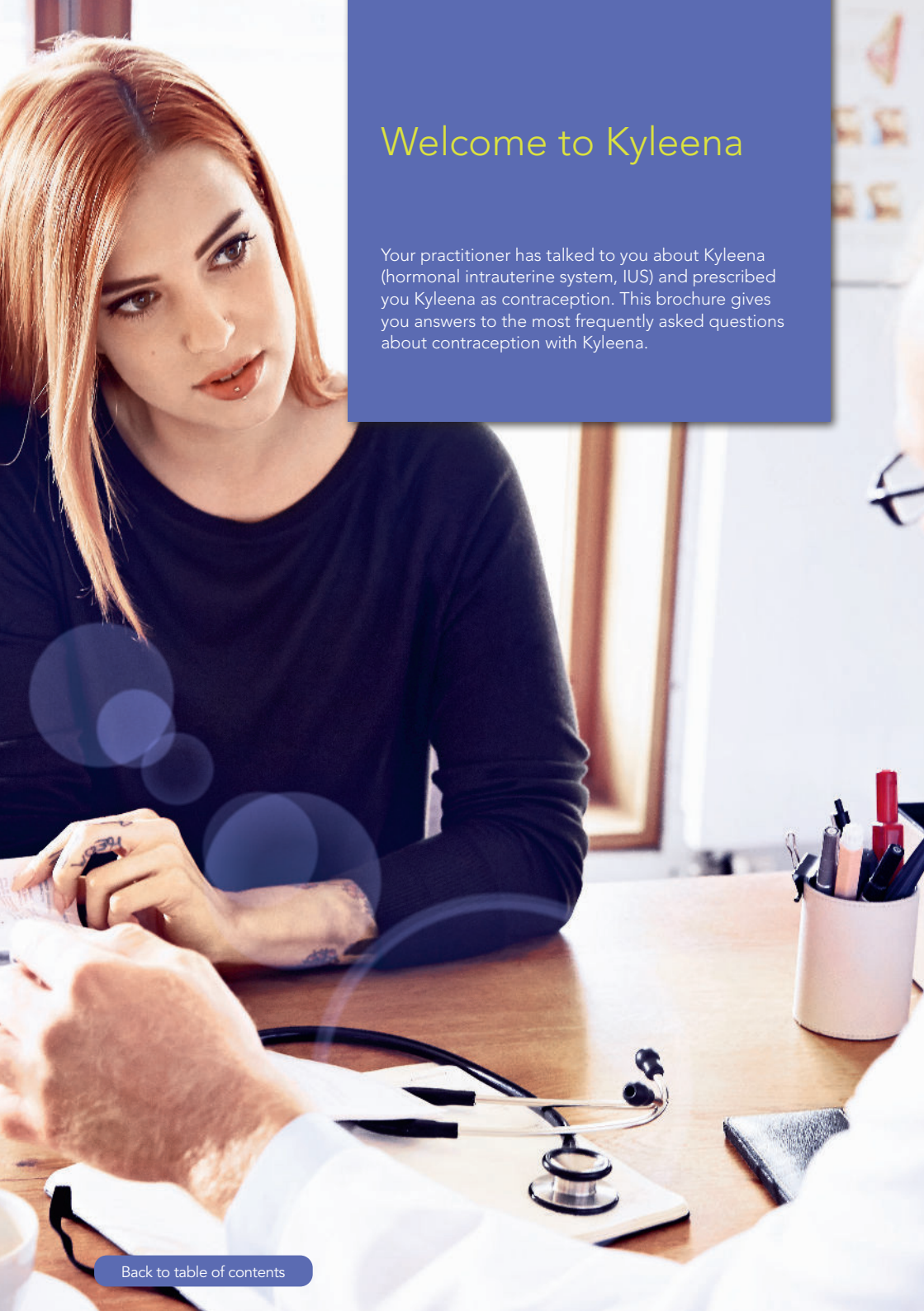
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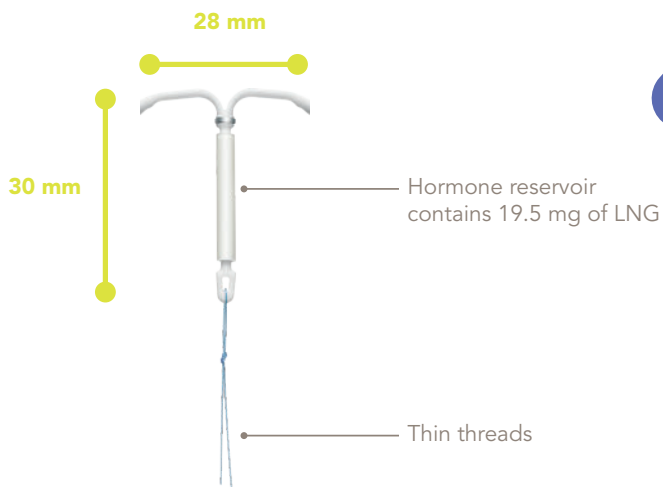
A woman with long, straight red hair is sitting at a wooden desk, looking down at a document. Her hands are resting on the desk, and she has a tattoo on her left forearm. In the foreground, a doctor's hands in a white coat are visible, holding a pen. A stethoscope lies on the desk. To the right, there is a pink cup holding various pens and markers. The background is slightly blurred, showing a window and some office equipment.

Welcome to Kyleena

Your practitioner has talked to you about Kyleena (hormonal intrauterine system, IUS) and prescribed you Kyleena as contraception. This brochure gives you answers to the most frequently asked questions about contraception with Kyleena.

What is Kyleena?

Kyleena is used to prevent pregnancy (contraception) for up to five years. Kyleena is a T-shaped hormonal IUS that gradually releases a small amount of the hormone levonorgestrel (LNG) once inserted into the womb. Kyleena is 28 x 30 mm in size. It has thin threads attached to it that your practitioner can use to remove Kyleena.



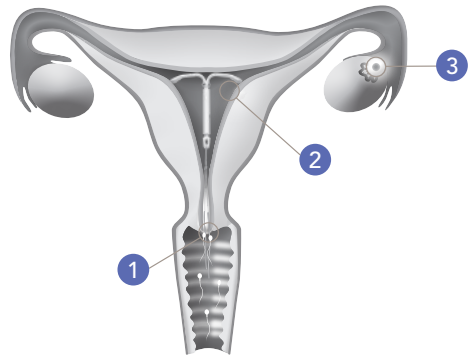
Were you shown a Kyleena demo? Ask your practitioner to show you what the Kyleena looks like.

How does Kyleena work?

Kyleena works by thickening the cervical mucus while also stopping the lining of the womb from building up. Together, this prevents an egg and sperm cell from coming into contact with each other, thus preventing fertilization.

Important aspects of Kyleena:

- Releases only a low dose of hormone
- Contains no estrogen
- Mostly does not affect your normal hormone cycle



- 1 Thickens the mucus in your cervix. This prevents sperm cells from penetrating it.
- 2 Reduces the monthly growth of the lining of the womb. Together, this prevents an egg and sperm cell from coming into contact with each other, thus preventing fertilization.
- 3 Because these effects are mainly local, ovulation (release of an egg from the ovary) usually continues while using Kyleena.



What you need to know about having it placed

How is Kyleena placed and how long does it take?

Placement normally takes no more than a few minutes. It starts out just like an internal examination you may have undergone before. A thin flexible tube containing Kyleena is then inserted into your womb. Once Kyleena is in the correct position, your practitioner will withdraw the insertion tube and Kyleena will remain in place. You may experience some pain and/or dizziness during placement. You can take a painkiller beforehand, as advised by the practitioner, before the placement of Kyleena.

After placement, you may experience some pain similar to menstrual cramps; in this case, a painkiller can be helpful. This generally disappears within a few hours. If you experience severe pain or heavy bleeding after Kyleena is placed or if pain/bleeding persists for more than a few weeks, make an appointment to see your practitioner.

When should Kyleena be placed?

Kyleena should be placed within seven days of the start of your period. You are then immediately protected against pregnancy. When replacing a hormonal IUS, there is no need to wait until your period.

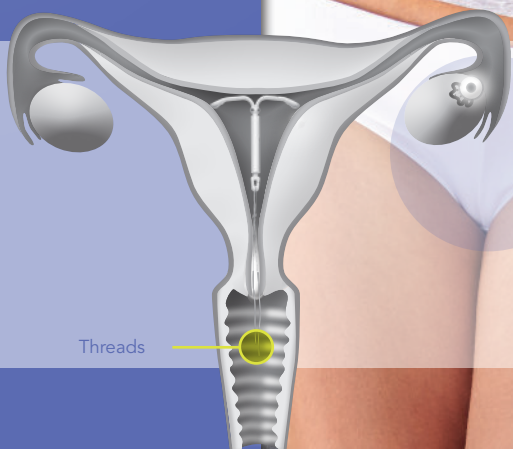
Is there a risk of perforation?

Perforation of the uterine wall may occur in some cases during Kyleena placement, although the perforation may not be discovered until a later time. If Kyleena ends up outside the womb, it is no longer effective at preventing pregnancy. Sometimes the IUS must be surgically removed in such cases. The risk of perforation is increased in breastfeeding women and in women who had their IUS placed up to 36 weeks after giving birth, and it may be increased in women with a womb that tilts backward.

Should Kyleena be checked after placement?

You should have your Kyleena checked 4-6 weeks after placement.

Kyleena in the womb



What are the threads attached to Kyleena for?

The two threads allow your practitioner to remove the Kyleena. Your practitioner can show you how to check that the threads are present. If you can feel the threads, Kyleena is still in place. If you have additional questions about the threads, you can discuss them with your practitioner.



What to expect: my first weeks with Kyleena

What effect may Kyleena have on my period?

Kyleena may affect your menstrual cycle. It can alter your period so you may experience spotting (irregular light bleeding), longer or shorter periods, lighter or heavier bleeding, or no bleeding at all.

During the first 3-6 months, you may experience more bleeding and spotting between periods. Sometimes the bleeding is heavier than usual at first.

After that, you are likely to experience a gradual reduction in bleeding during menstruation and a decrease in the number of days of menstruation. Some women eventually stop menstruating altogether.

- This is due to the way Kyleena works: the hormone levonorgestrel reduces the monthly thickening of the lining of the womb, preventing pregnancy. There is also no need for the lining of the womb to shed during menstruation. Just because you don't get your period anymore doesn't mean you won't be fertile in the future. Your natural hormone levels usually remain normal.
- Not getting your period is not necessarily a sign of pregnancy. But if your period stays away and you also have other symptoms of pregnancy, you should have your practitioner examine you and take a pregnancy test.

- If you haven't had your period for six weeks and are worried, consider taking a pregnancy test. If it is negative and you have no other signs of pregnancy, you do not need to repeat the pregnancy test.

At the back of this brochure you will find a menstrual diary. This will help you keep track of changes in your monthly cycle.

When Kyleena is removed, your periods should quickly return to normal.

Can I use tampons or a menstrual cup?

Use of sanitary pads is recommended. If you use tampons or a menstrual cup, you should change them carefully so you don't pull on the Kyleena threads.

Will Kyleena affect sexual intercourse?

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



What else should I know about Kyleena?

How will Kyleena affect my skin?

As with other hormonal contraceptives, acne can occur after placement of Kyleena.

Because Kyleena works mainly locally and it does not contain an estrogen hormone, Kyleena is unlikely to directly affect your skin.

However, if you have previously used another hormonal contraceptive method to improve the condition of your skin, acne may occur when you switch to Kyleena.

Does Kyleena affect my ovaries?

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

It is possible that while using Kyleena, your practitioner may discover such a cyst as an incidental finding during a vaginal ultrasound. Ovarian cysts are temporary and harmless in the vast majority of cases. In rare cases, medical attention may be necessary or, in even rarer cases, surgery.

Can Kyleena affect my fertility?

After Kyleena is removed, you are as fertile again as if you had not used Kyleena.

Kyleena can be removed at any time. This means that if you plan to become pregnant, Kyleena can be easily removed by your practitioner. Once Kyleena is removed, you can immediately try to get pregnant.

Is there a risk of ectopic pregnancy with Kyleena?

Becoming pregnant while using Kyleena is rare. However, if you become pregnant while using Kyleena, the risk that the pregnancy could develop outside the womb (an ectopic pregnancy) is increased. Women who have already had an ectopic pregnancy or who have had surgery on the fallopian tubes, or who have had a pelvic infection are at higher risk for this type of pregnancy. An ectopic pregnancy is a serious condition requiring immediate medical intervention and can affect future fertility. You should tell your practitioner if you are experiencing lower abdominal pain, especially if you have skipped a period (and had regular periods before) and/or have unexpected bleeding and/or pregnancy symptoms, as this may indicate an ectopic pregnancy.

Is there a risk of infection with Kyleena?

Kyleena, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or other STIs. Condoms are recommended to prevent STIs.

The insertion tube and the IUS itself are sterile. Nevertheless, there is an increased risk of infection in the lesser pelvis (infection of the lining of the womb or fallopian tubes) during placement and for the first three weeks after placement. Infections in the lesser pelvis in IUS users are often associated with the presence of sexually transmitted infections (STIs). The risk of infection is increased if you or your partner have different partners, or if you have had previous inflammatory disease in the lesser pelvis (PID: *pelvic inflammatory disease*). Infections in the lesser pelvis should be treated immediately.

Your practitioner will perform a complete examination prior to placement to ensure there are no existing infections.

Does Kyleena protect against sexually transmitted infections (STIs)?

Kyleena does not protect against any STIs, including HIV/AIDS. For protection against STIs, it is recommended to use a condom.

Can Kyleena fall out?

Although unlikely, it is possible for Kyleena to be partially or completely expelled. If that happens, you are not protected against pregnancy. An unusual increase in the amount of blood during your period or the occurrence of pain may be a sign that this has happened. Feeling the threads may reassure you that Kyleena is still in place.

If you think Kyleena has come out of place, use a non-hormonal contraceptive method (such as condoms) and then make an appointment with your practitioner.

What happens after five years? How is Kyleena removed?

Kyleena should not be left in place for more than five years. Kyleena can be easily removed by your practitioner at any time. After Kyleena is removed, you are as fertile as before.

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

What happens if I want to become pregnant?

Kyleena can be removed at any time and your normal fertility level should return after removal.

Can Kyleena be used when breastfeeding?

The daily dose of the hormone in the hormonal IUS and the amount in your blood are lower than when using the contraceptive pill. When using the hormonal IUS, only very low hormone levels are measured in breast milk (0.1% of the dose is transferred to the infant). Therefore, the hormonal IUS may be used if you are breastfeeding.

The risk of perforation is increased in breastfeeding women and in women who had their IUS placed up to 36 weeks after giving birth.



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If you want to continue using Kyleena after five years, your practitioner can remove it and place a new one.

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Where can I get more information?

This brochure is not a substitute for the package leaflet. If you have additional questions, please ask your practitioner.

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Kyleena menstrual diary

You can use this menstrual diary to track changes in your cycle, record your periods and any other bleedings that occurs between periods. This can be indicated in the appropriate box (day) on the calendar, in the following manner:

- No bleeding:
Leave empty
- Spotting:
Place a dot
- ✕ Normal bleeding:
Place an X
- Severe bleeding:
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 undergo a checkup within 4-6 weeks of Kyleena placement

Notes

[illegible]

Patient name:

Date of placement:

Name of practitioner:

Practitioner phone number:

For more information, consult the package leaflet, also available at:
<https://pharma.bayer.nl/geneesmiddelen/kyleena>



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