

 Kyleena®



User guide



Contents

You and your doctor have together chosen for you Kyleena for contraception.

This guide will tell you

- how Kyleena **works**
- how Kyleena is **inserted**
- how Kyleena **affects your bleeding pattern**
- answers to **frequently asked questions** about Kyleena.



What is Kyleena?

- Kyleena is a small hormonal contraceptive made of flexible plastic and placed into the womb. Kyleena prevents pregnancy for up to 5 years, after which it should be removed or replaced.
- Kyleena is a low-hormone contraceptive. It contains 19.5 mg of progesterone (levonorgestrel) that is slowly released into the womb in small amounts at a constant rate. The hormonal activity of Kyleena users remains unchanged.
- Levonorgestrel released into the womb reduces menstrual bleeding significantly.
- Kyleena contains no estrogen and thus does not increase the risk of blood clots.
- Kyleena is suitable for both women who have not given birth and women who have given birth.

This is how Kyleena works

Kyleena has a local effect

When Kyleena is in place, it slowly releases very small amounts of levonorgestrel into the womb at a constant rate. Kyleena has mainly a local effect in the womb where it is placed and where the contraceptive effect is required. Only a very small amount of the hormone enters the bloodstream. For this reason hormonal activity remains unchanged and the ovaries function normally during the use of Kyleena. Also ovulation (the release of an egg) is usually not affected.

Kyleena provides effective contraception

Kyleena is one of the most reliable contraceptive methods. It is more than 99.7 % effective. Kyleena prevents pregnancy up to five years.

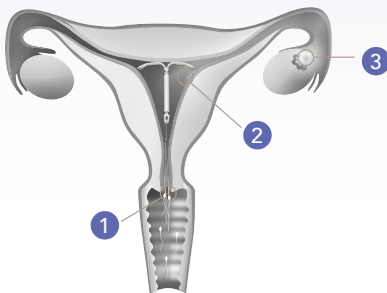
Kyleena does not protect from HIV or other sexually transmitted diseases. It is important to protect yourself by using condoms.

The onset of contraception is rapid

The IUS is primarily placed within 7 days of the start of your monthly period – thus the IUS has an immediate contraceptive effect. If the IUS is placed at another phase of the menstrual cycle, the contraceptive efficacy does not start immediately. You should then use additional contraceptive measures (condom) for 7 days.

This is how Kyleena prevents pregnancy

Kyleena prevents fertilization. This prevention of pregnancy is not based on an abortive effect.



- 1** Progesterone (levonorgestrel) contained in Kyleena causes the cervical mucus in the uterine cervix to thicken which prevents the sperm from entering the womb.
- 2** Should any sperm succeed in overcoming this barrier, the movement and functioning of the sperm in the uterine cavity is inhibited by progesterone. Kyleena reduces the monthly growth of the inner lining of your womb, which decreases menstrual bleeding. In some women menstrual bleedings will stop altogether, which is harmless.
- 3** Hormonal activity remains unchanged: ovulation (release of the egg) is usually not affected and the ovaries produce the same hormones as before the placement of Kyleena.

This is how Kyleena is inserted

Kyleena is placed by a doctor or a nurse at the clinic. The insertion procedure usually takes a few minutes. Kyleena is inserted into the womb via a thin, flexible plastic tube called inserter. The placement may cause some pain that resembles menstrual pain and usually disappears quickly. After the insertion you can move and function normally. Your doctor or nurse will schedule a follow-up visit for you. During the follow-up visit it is checked that Kyleena is correctly in place and has suited you well.

A few days after placement

When some time has passed from the placement, menstrual-like pain may occur. Take pain medication as needed. If you have severe pain or heavy bleeding after the placement or these continue for several weeks, you should contact your doctor before the next follow-up visit.

One month after placement

During the first month, a small risk of pelvic infection is associated with the placement of Kyleena. Such infections are usually related to sexually transmitted diseases, and they must be treated promptly. In rare cases Kyleena cannot be inserted in the correct place. Then its contraceptive efficacy is reduced and it must be removed.

When should I contact a doctor?

Contact a doctor if

- you have severe pain or heavy bleeding after Kyleena placement or these continue for several weeks after the placement;
- you think you may be pregnant*;
- you have persistent abdominal pain, fever, or unusual vaginal discharge;
- you or your partner feel pain or discomfort during intercourse;
- you experience sudden changes in your menstrual bleeding, for example if you first have little or no menstrual bleeding, and then you start having heavy and painful bleeding;
- you have migraine, exceptionally severe headache, sudden problems with vision, jaundice, or high blood pressure.

* Read more about pregnancy on page 11.

How will Kyleena affect my period?

Levonorgestrel that is locally released into the womb from Kyleena reduces the monthly growth of the uterine lining, which reduces bleeding. Often the duration and volume of menstrual bleeding is gradually reduced. However, some spotting or light bleeding may occur in addition to monthly periods for the first 3 to 6 months. Consult your doctor or nurse if bleeding remains heavier than usual or if the bleeding becomes heavy after it has been light for a while.

Sometimes periods may stop altogether. This is normal and not harmful. If your monthly period does stop while on Kyleena, it should return once Kyleena is removed. If you have not had a period for six weeks and think you might be pregnant, then consider having a pregnancy test. If the result is negative and you have no other symptoms of pregnancy (nausea, tiredness, breast tenderness, etc.), the test need not be repeated. If the result is positive, contact a doctor immediately.

Keeping track of bleedings and any possible spotting days might be useful during the first few months. You can use a menstrual diary for this.

Menstrual diary

Mark a dot (●) when you are spotting. Mark an (x) when your flow is normal.

Fill in the box (■) when your flow is heavy. Leave the box blank when you are not bleeding.

Month	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
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Questions that you may have:

Will Kyleena interfere with sexual intercourse?

Since Kyleena is placed in the womb, not the vagina, neither you nor your partner should feel Kyleena during sexual intercourse.

Can I use tampons or a mooncup with Kyleena?

Yes, you can, but remove them with care. Remove vacuum pressure from the moon cup before removing it. However, periods over time usually become lighter, or may stop, making the use of tampons or a moon cup unnecessary.

Does Kyleena cause weight gain?

According to studies, Kyleena does not seem to cause weight gain.

Can Kyleena fall out by itself?

While it is very unlikely, it is possible for Kyleena to fall out partially or completely. In such a case it no longer protects you against pregnancy. If you notice your bleeding is heavier than usual during your period, it may be a sign that Kyleena is not in the correct position. You should avoid intercourse or use for example condoms until you see your doctor or nurse.

What if I notice that I am pregnant while using Kyleena?

The contraceptive efficacy of Kyleena is very high and becoming pregnant while using Kyleena is very rare but still possible.

If you do not have periods while Kyleena is in place, this does not necessarily mean that you are pregnant. **If you also have other symptoms of pregnancy, for example, nausea, tiredness and breast tenderness, you should contact a doctor. If you have in addition to symptoms of pregnancy persistent bleeding or pain (especially in the lower abdomen) or you feel dizzy, this may indicate a pregnancy outside the womb. In such a case, immediately contact a doctor.**

What if I want to become pregnant?

If you are planning pregnancy, you can ask a doctor or nurse to remove Kyleena at any time. Pregnancy is possible in the next month following the removal.

In clinical studies it has been found that women who have used Kyleena are equally capable of becoming pregnant than those women who have never used Kyleena.

Can I breastfeed while using Kyleena?

Yes, you can.

Can I use Kyleena in between pregnancies?

Yes. Kyleena can be placed 6 weeks after delivery. Kyleena is often placed in connection with the postpartum check-up.

Who can use Kyleena?

Kyleena is suitable for preventing pregnancy in women of all ages – both women who have not given birth and women who have given birth.

Does the insertion of Kyleena hurt?

You may feel some pain during the placement of Kyleena. There are individual differences in pain sensitivity. The pain experienced during the placement of Kyleena is similar to menstruation pain and disappears quickly. The womb is a muscle which may contract after the placement of Kyleena.

How long can Kyleena be used?

The contraceptive efficacy of Kyleena lasts for five years. After this Kyleena must be removed or, if needed, replaced with a new one by a doctor or a nurse. The doctor or nurse can also remove Kyleena at any time earlier if your plans change and you wish to become pregnant.

How much hormones does Kyleena contain?

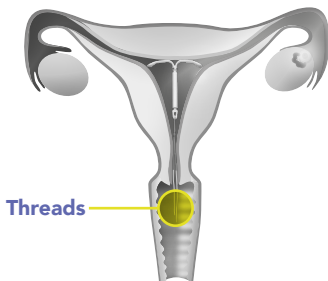
Kyleena contains a small dose of levonorgestrel with a local effect, and it does not contain any estrogen. Because of this no risk of blood clots is associated with its use.

How effective is Kyleena?

Kyleena is one of the most reliable contraceptive methods. It is more than 99.7 % effective.

Why does Kyleena have threads?

Kyleena contains two thin threads which are used by the doctor or nurse to remove the device. You can check whether Kyleena is still in place by feeling the threads.



Possible adverse effects of Kyleena

As with any drug, some women may experience side effects with Kyleena. Below is a list of adverse effects that may occur during the use of Kyleena, although not everybody gets them.

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

- Headache, abdominal / pelvic pain, acne / greasy skin, bleeding changes, including increased and decreased menstrual bleeding, spotting, infrequent bleeding, and absence of bleeding, ovarian cyst, inflammation of the external genital organs or vagina (vulvovaginitis)

Common (may affect up to 1 in 10 people)

- Depressed mood / depression, decrease in libido, migraine, dizziness, feeling sick (nausea), pelvic inflammatory disease, painful menstruation (dysmenorrhea), breast pain/discomfort, device expulsion (complete and partial), hair loss, genital discharge

More information on adverse effects related to the use of Kyleena is available in the patient information leaflet.

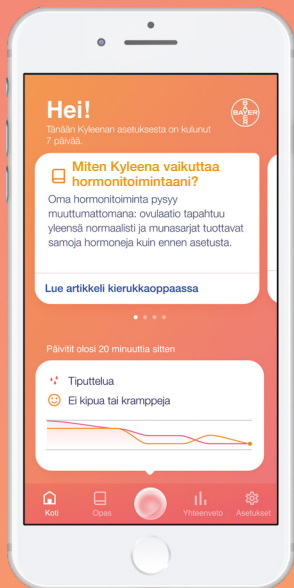
Bayer's Medinfo service
– don't hesitate to ask

Bayer's Medinfo will help you with all questions related to Bayer products on weekdays from 9 am till 3 pm.

☎ 020 785 21 ✉ medinfo@bayer.fi



Wonder



Free app for Kyleena users



You can find important information from the smart IUS guide based on your Kyleena insertion date.



Make entries and track easily changes in how you feel.

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Point your phone at the QR code of your application store and download Wonder. When Wonder asks for the name of the coil, enter **Kyleena** to the field and you can start using the app.

