Kyleena®

19,5 MG LEVONORGESTREL

Patient information

We hope that this brochure can provide answers to your questions and concerns about Kyleena®.

What is Kyleena®?

Kyleena® is an intrauterine device that consists of a hormone capsule attached to a soft T-shaped, tissue-friendly plastic device. The device is 28 mm wide and 30 mm long and is inserted into the uterus using an inserter.

Kyleena® is the smallest 5-year coil on the market and contains a low dose of progestin (synthetic progesterone). Your midwife or doctor will insert it into your uterus, where it will protect you against unwanted pregnancy. Thanks to the slow release of a low dose of levonorgestrel, a progestin (ave. 9 micrograms per 24 hours), locally in the uterus over a period of 5 years, you will not need to think about daily, weekly or monthly contraception.

How does Kyleena® work?

When Kyleena® is in place in your uterus, it releases a low dose of levonorgestrel, a progestin, slowly and continuously, protecting you against pregnancy in three ways.

1. Kyleena® thickens the cervical mucous, inhibiting sperm movement.

2. Kyleena® affects growth of the endometrial mucous membrane. The membrane becomes thinner and infertile.

3. The device also creates a non-beneficial environment for sperm in the uterus and Fallopian tubes. Sperm movement is inhibited and conception is prevented.

How effective is Kyleena®?

Kyleena® is one of the most effective contraceptives providing over 99% protection against pregnancy from the time it is inserted into the uterus until it is withdrawn. Kyleena® is active for up to 5 years.

What is the function of the hormone progestin?

Kyleena® mainly acts locally in the uterus. It releases progestin into the uterus and only very small amounts pass into the blood. Levonorgestrel is the most commonly-used progestin in contraceptives. Kyleena® does not affect ovulation in most women. That means that the natural production of oestrogen by the ovaries is maintained. For more information on the side effects from using Kyleena®, see further down in this brochure and the pack insert included in the packaging.

What are the threads attached to Kyleena® for?

The threads attached to Kyleena® are there for your midwife or doctor to withdraw the device. Your midwife or doctor will tell you how you feel that the threads are in place.
By being able to feel the threads, you can check that Kyleena® is still in place in the uterus, and giving you effective protection. If you have other questions on the threads, please talk to your midwife or doctor.

Do NOT use Kyleena if:

- you are pregnant (see the section on "Pregnancy, breastfeeding and fertility")
- have pelvic inflammation (infection of the female reproductive organs) or have had recurring instances of the same.
- have increased susceptibility to infections in the reproductive organs
- have an infection in the lower genitals, e.g. an infection of the vagina or cervix
- have had an infection of the uterus after giving birth, an abortion or miscarriage within the last three months
- have cervical cell changes
- have cancer or suspected cancer in the cervix or uterus
- have tumours that are sensitive to progestin hormones for growth, e.g. breast cancer
- have inexplicable bleeding from the uterus
- have any malformation of the cervix or uterus, including myomas (tumours in the muscle of the uterus) if they affect the uterine cavity
- have a liver disease or liver tumour
- are allergic to levonorgestrel or any of its active ingredients (listed in section 6).

Your first few days with Kyleena®

Important information you should have before having Kyleena® inserted

How is Kyleena® inserted?

When you decide to have Kyleena®, it can be inserted at your next visit to your midwife or doctor. Kyleena® is inserted as part of a gynecological examination using a flexible insertion tube. Once Kyleena® is inserted, the threads are cut to a length of 2 – 3 cm.

What should I expect directly after insertion?

Most women find insertion relatively simple, but some can experience slight pain and dizziness during insertion. If you experience severe pain or pain does not abate after a few weeks, contact your midwife or doctor.

How quickly will Kyleena® protect against pregnancy?

If you insert Kyleena® within 7 days of the first day of your menstruation, Kyleena® will provide effective protection against pregnancy for up to 5 years. If Kyleena® is inserted at any other point during your menstruation cycle, use a condom for extra protection for the first 7 days.

You do not need to think about daily, weekly or monthly contraceptive protection with Kyleena®.

Your first month with Kyleena®

Important information you should have before having Kyleena® inserted

Are there other reasons why I should contact my midwife or doctor?

Contact your midwife or doctor if any of the following occur:

- You experience severe pain or heavy bleeding after insertion, or pain or bleeding continue for more than 5 weeks.
- You think you might be pregnant.
- You have persistent abdominal pains, fever or abnormal discharge
- You or your partner feel pain or discomfort during sexual intercourse.
- You experience a change in bleeding pattern (you have little or no bleeding, which then suddenly becomes heavy and persistent).
- You experience other medical problems (e.g. migraine/very severe headaches, sudden problems with your vision, jaundice or high blood pressure.

Here are other things you ought to know when using Kyleena®

How will Kyleena® affect my bleeding patterns? Will I have bleedings every month?

Your menstruation will get lighter, in terms of bleeding and the number of days per month. You can experience spotting or light bleeding for the first 3–6 months after having Kyleena® inserted. Some women can experience longer or heavier bleeding during this period, but that does not mean that you will bleed every day. We recommend keeping a record of when you experience bleeding, so that you can see the subsequent improvement (there is a bleeding calendar at the end of this brochure).

Talk to your midwife or doctor if your bleeding continues to be heavier than normal, or if you suddenly begin to bleed several more daysthan before.

Some women can find that their periods stop completely when using Kyleena®. If you have not had any bleeding within the last 6 weeks and are worried about being pregnant, take a pregnancy test. If the test is negative, you do not need to take any more tests if you do not have any other symptoms that could indicate pregnancy (such as nausea, tiredness or swollen breasts). If you stop menstruating while using Kyleena®, it will return again when Kyleena® is removed.

Will Kyleena® affect my sex life?

Once Kyleena® is in place in the uterus, neither you nor your partner will feel it during sexual intercourse.

Your future with Kyleena®

Should I keep a record of my bleeding patterns?

Because you may notice a difference in your bleeding, it may be a good idea to keep a record of your bleeding/spotting to help you and your midwife or doctor to track your experience of Kyleena®. You will find a bleeding calendar at the end of this brochure.

What if I decide to have children?

Kyleena® protects against pregnancy for up to 5 years, but you can ask your midwife or doctor to remove it any time. You can try to become pregnant as soon as your Kyleena® is removed. Most women in clinical studies who wanted to become pregnant after Kyleena® was removed succeeded within 1 year, which is the same rate as for women not using contraceptives.

If you want to get pregnant

Worth remembering when planning pregnancy

The National Food Agency in Sweden recommends an intake of 400 micrograms of folic acid every day from one month before conceiving and for at least the first 12 weeks of pregnancy. This is to prevent spinal hernia in the baby. A sufficient level of folic acid remains important throughout pregnancy, for the mother's blood cell formation and foetal development. (National Food Agency, Sweden 2018).

Frequently asked questions on coils

Can I use tampons when I have a coil?

Yes, but be careful when pulling out a tampon to avoid catching the threads attached to the coil.

Can I take out a coil at any time?

Yes. You can ask your midwife or doctor to remove your coil whenever you want, but you are not protected against pregnancy after it has been removed.

Can a coil fall out?

A coil can fall out partially or completely, but it is highly unusual. If you think that your bleeding level has returned to that before you had a coil, you should check that it is correctly in place in your uterus. If your bleeding starts to become irregular after it was regular, it can be a sign that your coil has partially fallen out. If your coil falls out, you are no longer protected against pregnancy. You should avoid sexual intercourse or use a condom and consult your midwife or doctor.

Can a coil cause me to gain weight?

Neither hormonal or copper coils cause an increase in weight.

Is it possible to see which sort of coil is used when it's in place in the uterus?

Health care personnel can tell the difference between different types of coil using ultrasound or x-ray. The difference between progestin coils is that there is a silver ring (nickel-free) on the smaller ones, and Kyleena has blue threads (brown on other progestin coils).

Will a coil protect against sexually-transmitted diseases?

No. Coils are used to protect against unwanted pregnancy and do not provide protection against sexually-transmitted diseases, including HIV and AIDS. Using a hormonal coil seems to give a certain amount of protection against infections rising upwards, probably through effect on to mucous in the cervix, which becomes impenetrable for bacteria, and on the uterine mucous membrane. It is important that you use a condom for protection against sexually-transmitted diseases.

What happens if I get a sexually-transmitted disease?

If you think you have been infected with a sexually-transmitted disease when using a coil, you should contact your midwife or doctor. You should avoid having sexual intercourse until you have seen your midwife or doctor.

Can I use a coil if I have not had a child?

Hormonal and copper coils are recommended for young women, including those who have never been pregnant. Experience of using a coil is currently limited for the very young (teenagers), but a coil according to individual choice can be an alternative.

Can I use a Kyleena when I am breastfeeding?

Yes. Kyleena secretes a low dose of progestin and is very suitable for use during breastfeeding. It contains no oestrogen. Progestin passes into breast milk, but the amount is very small and has not proven to have any negative effect on the child.

Can I use a coil between births?

Yes, but a coil cannot be fitted any earlier than 6 weeks after birth, after which it gives safe prevention. You can try to become pregnant again as soon as your midwife or doctor removes your coil.

Can I become pregnant when using a coil?

The risk of becoming pregnant when you are using a coil is very low, but it can happen. If you do not experience any menstrual bleeding when you have a hormonal coil inserted does not usually mean that you are pregnant. If you do not have menstrual bleeding as expected, and have other symptoms that can indicate pregnancy (such as nausea, tiredness, swollen breasts), you should directly contact your midwife or doctor. If you become pregnant, there is a risk of a pregnancy outside the uterus. The following signs and symptoms can indicate a pregnancy outside the uterus:

- Your menstruation has stopped and you suddenly experience persistent bleeding and abdominal pains.
- You have severe or persistent pain in the lower abdomen.
- You have normal pregnancy symptoms, but can also bleed and feel dizzy.

If you experience any of the above, contact your midwife or doctor immediately.

What are the most common side effects with Kyleena®?

As with all medical products, Kyleena can cause side effects, but not all users experience them. Very common side effects (occurring in 1 or more out of 10 women) include headaches, abdominal and pelvic pains, acne or greasy skin, changes in bleeding patterns, cysts on the ovaries, inflammation in the outer genitals or vagina (vulvovaginitis).

Always tell your doctor that you are using Kyleena® whenever you have a consultation.

Kyleena®, intrauterine device, 19.5 mg levonorgestrel

Indications: Contraception for up to 5 years. Side effects: Headaches, abdominal/pelvic pain, acne/greasy skin and changes in bleeding pattern. **Warnings/caution**: Kyleena should be used with caution or removed, after consultation with a specialist, if any of the following conditions exist or occur for the first time: very severe headaches, focal migraine with asymmetric loss of vision, jaundice, high blood pressure, stroke or heart infarction. Women considering having Kyleena inserted should be informed of the signs and symptoms of perforation as well as the risk of ectopic pregnancy. Mood changes and depression are well-known side effects when using hormonal contraceptives. Women should be advised to contact a doctor in case of mood changes or depressive symptoms.. Before prescribing, please read the Summary of Product Characteristics at Fass.se contraceptive device G02BA03. Rx. F. For details and price, go to www.fass.se SPC 2019-04-29.

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