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. So, if you choose 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.[1]

What are the side effects of Kyleena®?[1]

Kyleena® is generally well tolerated, but as your body adapts to it, you may experience some side effects. The following are some of the more common side effects that you may experience, headache, acne/greasy skin, bleeding changes, abdominal pain, ovarian cyst. As your body becomes used to Kyleena® these side effects will tend to disappear.
Please talk to your healthcare professional, if you have any concerns about potential side effects.

Where can I get more information?

We hope this brochure was helpful. If you have additional questions, please ask your healthcare professional or visit www.medicines.ie for further information.

Reference
1. Kyleena® SmPC www.medicines.ie

Abbreviated Prescribing Information:
Kyleena 19.5 mg intrauterine delivery system. See full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** The product consists of a whitish or pale yellow drug core (19.5mg levonorgestrel) covered with a semi-opaque membrane, which is mounted on the vertical stem of a T-body. In addition, the vertical stem contains a silver ring located close to the horizontal arms. **Indication:** Contraception for up to 5 years. Dosage and administration: Insertion into the uterine cavity using aseptic technique by physicians/ healthcare providers who are experienced in IUS (intrauterine delivery system) insertions and/or have undergone training on the Kyleena insertion procedure. Follow full instructions for preparation for insertion, insertion and removal/replacement, particularly with regard to timing and positioning. Kyleena can be distinguished from other IUSs by the combination of the visibility of the silver ring on ultrasound and the blue colour of the removal threads. The T-frame of Kyleena contains barium sulphate which makes it visible in X-ray examination. The system should be removed no later than by the end of the fifth year. If the woman wishes to continue using the same method, a new system can be inserted immediately following removal of the original system. If pregnancy is not desired, the removal should be carried out within 7 days of the onset of menstruation, provided the woman is experiencing regular menses. After removal of Kyleena, the system should be examined to ensure that it is intact. Elderly patients: Kyleena has not been studied in women over the age of 65 years. There is no indication for the use of Kyleena in postmenopausal women. Paediatric population: Use of this product before menarche is not indicated. **Contraindications:** Pregnancy; acute or recurrent pelvic inflammatory disease (PID) or conditions associated with increased risk for pelvic infections; acute cervicitis or vaginitis; postpartum endometritis or infected abortion during the past three months; cervical intraepithelial neoplasia until resolved; uterine or cervical malignancy; progestogen-sensitive tumours, e.g. breast cancer; abnormal vaginal bleeding of unknown aetiology; congenital or acquired uterine anomaly including fibroids which would interfere with insertion and/or retention of the IUS (i.e. if they distort the uterine cavity); acute liver disease or liver tumour; hypersensitivity to the active substance or to any of the excipients. **Warnings and Precautions:** Use with caution after specialist consultation, or consider removal of the system if any of the following conditions exist or arise for the first time: migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; jaundice; marked increase in blood pressure; severe arterial disease such as stroke or myocardial infarction. May affect glucose tolerance, monitor the blood glucose concentration in diabetic users. However, there is generally no need to alter the therapeutic regimen in diabetics using levonorgestrel - IUS. Medical examination/consultation: Before insertion, a woman must be informed of the benefits and risks of Kyleena, including the signs and symptoms of perforation and the risk of ectopic pregnancy, see below. A physical examination including pelvic examination, examination of the breasts, and a cervical smear should be performed. Pregnancy and sexually transmitted diseases should be excluded. Genital infections should be successfully treated prior to insertion. The position of the uterus and the size of the uterine cavity should be determined. Fundal positioning of Kyleena is important in order to maximize the efficacy and reduce the risk of expulsion. Insertion and removal may be associated with some pain and bleeding. The procedure may precipitate a vasovagal reaction (e.g. syncope, or a seizure in an epileptic patient). A woman should be re-examined 4 to 6 weeks after insertion to check the threads and ensure that the system is in the correct position. Follow-up visits are recommended once a year thereafter, or more frequently if clinically indicated. Kyleena is not for use as a post-coital contraceptive. The use of Kyleena for the treatment of heavy menstrual bleeding or protection from endometrial hyperplasia during oestrogen replacement therapy has not been established. Ectopic pregnancy: In clinical trials, the overall incidence of ectopic pregnancy with Kyleena was approximately 0.20 per 100 woman-years. Approximately half of the pregnancies that occur during Kyleena use are likely to be ectopic. For women who become pregnant while using Kyleena, the possibility of an ectopic pregnancy must be considered and evaluated. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection carry an increased risk of ectopic pregnancy. Because an ectopic pregnancy may impact future fertility the benefits and risks of using Kyleena should be carefully evaluated on an individual basis. Effects on the menstrual bleeding pattern: Effects on the menstrual bleeding pattern are expected in most users of Kyleena. Those alterations are a result of the direct action of levonorgestrel on the endometrium and may not correlate with the ovarian activity. Irregular bleeding and spotting are common in the first months of use. Thereafter, the strong suppression of the endometrium results in the reduction of the duration and volume of menstrual bleeding. Scanty flow frequently develops into oligomenorrhea or amenorrhea. Pregnancy should be considered if menstruation does not occur within six weeks of the onset of previous menstruation. A repeated pregnancy test is not necessary in subjects who remain amenorrheic unless indicated by other signs of pregnancy. Pelvic infection: Pelvic infection has been reported during use of any IUS or IUD. In clinical trials, PID was observed more frequently at the beginning of Kyleena use. Before electing use of Kyleena, patients should be fully evaluated for risk factors associated with pelvic infection (e.g. multiple sexual partners, sexually transmitted infections, prior history of PID). As with other gynaecological or surgical procedures, severe infection or sepsis (including group A streptococcal sepsis) can occur following IUD insertion, although this is extremely rare. If a woman experiences recurrent endometritis or PID or if an acute infection is severe or does not respond to treatment, Kyleena must be removed. Expulsion: In clinical trials with Kyleena, the incidence of expulsion was low (<4% of insertions) and in the same range as reported for other IUDs and IUSs. Symptoms of partial or complete expulsion of Kyleena may include bleeding or pain. However, the system can be expelled from the uterine cavity without the woman noticing it, leading to loss of contraceptive protection. As Kyleena decreases menstrual flow, increase of menstrual flow may be indicative of an expulsion. Risk of expulsion is increased in: Women with history of heavy menstrual bleeding; Women with greater than normal BMI at the time of insertion; this risk increases gradually with increasing BMI. Women should be counselled on possible signs of expulsion and how to check the threads of Kyleena and advised to contact a healthcare professional if the threads cannot be felt. A barrier contraceptive (such as a condom) should be used until the location of Kyleena has been confirmed. Partial expulsion may decrease the effectiveness of Kyleena. A partially expelled Kyleena should be removed. A new system can be inserted at the time of removal, provided pregnancy has been excluded. Perforation: Perforation or penetration of the uterine corpus or cervix by an intrauterine contraceptive may occur, most often during insertion, although it may not be detected until sometime later, and may decrease the effectiveness of Kyleena. In case of a difficult insertion and/or exceptional pain or bleeding during or after insertion, the possibility of perforation should be considered and appropriate steps should be taken, such as physical examination and ultrasound. Such a system must be removed; surgery may be required. Physical examination may not be sufficient to exclude partial perforation. A large prospective comparative non- interventional cohort study in users of other IUDs (N=61,448 women) with a 1-year observational period, showed that both breastfeeding at the time of insertion and insertion up to 36 weeks after giving birth were associated with an increased risk of perforation. Both risk factors were independent of the type of IUD inserted. Extending the observational period to 5 years in a subgroup of this study (N=39009 women inserted with another levonorgestrel- IUS or copper IUD, 73% of these women had information available over the complete 5 years of follow-up), the incidence of perforation detected at any time during the entire 5-year period was 2.0 (95% CI: 1.6-2.5) per 1000 insertions. Breastfeeding at the time of insertion and insertion up to 36 weeks after giving birth were confirmed as risk factors also in the subgroup that were followed up for 5 years. The risk of perforations may be increased in women with fixed retroverted uterus. Re-examination after insertion should follow the guidance given under the heading "Medical examination/consultation" which may be adapted as clinically indicated in women with risk factors for perforation. Lost threads: If the removal threads are not visible at the cervix on follow-up examinations, unnoticed expulsion and pregnancy must be excluded. Ultrasound or, if appropriate, x-ray may be used to ascertain the correct position of Kyleena. Ovarian cysts/enlarged ovarian follicles: Sometimes atresia of the follicle is delayed and folliculogenesis may continue. These enlarged follicles cannot be distinguished clinically from ovarian cysts and have been reported in clinical trials as adverse drug events in approximately 22.2 % of women using Kyleena including ovarian cyst, hemorrhagic ovarian cyst and ruptured ovarian cyst. Should an enlarged follicle fail to resolve spontaneously, continued ultrasound monitoring and other diagnostic/therapeutic measures may be appropriate. Psychiatric disorders: Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment. **Interactions:** Interactions can occur with medicinal products that induce microsomal enzymes, which can result in increased clearance of sex hormones. Substances known to increase the clearance of levonorgestrel are Phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin, and products containing St. John's wort. The influence of these medicinal products on the efficacy of Kyleena is not known. Many HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors when co-administered with sex hormones can have variable effects on the clearance of levonorgestrel (i.e. increase or decrease plasma concentrations of the progestin). Magnetic resonance imaging (MRI): Non-clinical testing has demonstrated that a patient can be scanned safely after placement of Kyleena under the following conditions: Static magnetic field of 3-Tesla or less, maximum spatial gradient magnetic field of 36000-Gauss/cm or less and maximum whole body averaged specific absorption rate (SAR) of 4 W/kg in the First Level Controlled mode for 15 minutes of continuous scanning. **Fertility, pregnancy and lactation:** Fertility: The use of a levonorgestrel-releasing intrauterine system does not alter the course of future fertility. Upon removal of the intrauterine system, women return to their normal fertility. Pregnancy: The use of Kyleena during an existing or suspected pregnancy is contraindicated. If the woman becomes pregnant while using Kyleena, the system should be removed as soon as possible, since any intrauterine contraceptive left in situ may increase the risk of abortion and preterm labour. Removal of Kyleena or probing of the uterus may also result in spontaneous abortion. Ectopic pregnancy should be excluded. Clinical experience of the outcomes of pregnancies under Kyleena treatment is limited due to the high contraceptive efficacy. Breast-feeding: A levonorgestrel-releasing IUS does not affect the quantity or quality of breast milk. Small amounts of progestogen (about 0.1 % of the levonorgestrel dose) pass into the breast milk in nursing mothers. **Effects on ability to drive and use machines:** Kyleena has no known influence on the ability to drive or use machines. **Undesirable Effects:** Very common: headache, abdominal/pelvic pain, acne/seborrhoea, bleeding changes including increased and decreased menstrual bleeding, spotting, infrequent bleeding and amenorrhoea, ovarian cyst, vulvovaginitis; Common: depressed mood/depression, decreased libido, migraine, dizziness, nausea, alopecia, upper genital tract infection, dysmenorrhea, breast pain/discomfort, device expulsion (complete and partial), genital discharge, increased weight; Uncommon: hirsutism, uterine perforation. With the use of levonorgestrel-IUS, cases of hypersensitivity including rash, urticaria and angiooedema have been reported. **Marketing Authorisation Number: PA 1410/081/001. Marketing Authorisation Holder/ Further information available from:** Bayer Limited, 1st Floor, The Grange Offices, The Grange. Brewery Road, Stillorgan, Co. Dublin, A94 H2K7. Tel.: (01) 2163300. **Classification for sale or supply:** prescription only. **Date of preparation: 11/2022.** Approval number: MA-KYL-IE-0001-1

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Kyleena®

19.5MG INTRAUTERINE DELIVERY SYSTEM
LEVONORGESTREL

A guide to your Kyleena®

Made by Bayer

This leaflet is intended for women who have been prescibed Kyleena®. Please read the patient information leaflet (PIL) included in your Kyleena® box for full details.

You've been given this booklet because you have chosen Kyleena®, a small intrauterine system (IUS) that sits in your womb to prevent pregnancy.

Kyleena®:[1]

- **An IUS, which is a long-acting reversible contraception (LARC)**
- **Releases a low dose of hormone**
- **Does not contain oestrogen**
- **Can be used regardless of whether you've had a baby or not**
- **Suitable for eligible women of all ages in need of contraception**

This is Kyleena®:[1]

*Not actual size

A small, flexible, plastic T-shape that sits in your womb. Once fitted, you shouldn't even know it's there.

How effective is Kyleena®?[1]

Kyleena is more than 99% effective with "perfect use" meaning that less than one woman in every 100 who uses this method for one year will become pregnant.

Kyleena® provides effective contraception for up to 5 years, but you can have it taken out sooner.

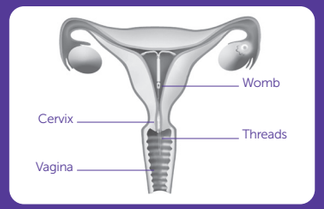
Will I be protected immediately?[1]

If Kyleena® is fitted **within 7 days from the start of your period**, you will be protected against pregnancy **straight away**.

How does Kyleena® work?[1]

Kyleena® slowly releases a **small amount of hormone**, a progestogen called levonorgestrel. As Kyleena® is placed in the womb, it works right where it is needed and only very small amounts of hormone will enter your bloodstream.

Ovulation (the release of an egg from the ovaries) usually continues while using Kyleena®.



Kyleena® prevents pregnancy by:[1]

- **thickening the mucus of your cervix, preventing the sperm getting through to fertilise an egg**
- **thinning of the lining of your womb, making it difficult for an egg to attach**

What happens at your fitting appointment?[1]

Placing Kyleena® should take no longer than a few minutes, but you will have a longer appointment so that your doctor or nurse can talk you through everything, ensure you are not pregnant and make sure you are happy to proceed.

When you are comfortable and ready, Kyleena® is placed in the womb using a thin tube.

Your doctor or nurse will teach you how to check that your Kyleena® is in place by finding and feeling the threads.

Will it hurt?[1]

You may experience some pain and/or dizziness during or after placement which usually settles down quickly. 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

Once it is fitted, **you should not be able to feel your Kyleena®.**

What happens afterwards?[1]

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 doctor or nurse.

You should be offered a check-up 4-6 weeks after placement to make sure everything is going okay.

At the end of the fifth year, your Kyleena® should be taken out by your doctor or nurse. If you wish to continue using Kyleena®, you can get a new one placed during the same appointment.

Will my periods change?[1]

Every woman is different, but Kyleena® is likely to affect your menstrual cycle, especially during the first 3-6 months after placement. The bleeding that can occur may include spotting and bleeding between your regular periods while your womb adjusts to Kyleena®.

However, a few months after this, **you may find that your periods become lighter, shorter, or stop altogether**. This is normal.

Can I still use tampons?[1]

Yes, as Kyleena® sits in the womb rather than the vagina, you can continue to use tampons. You should change them with care so as not to pull the threads of Kyleena®. The use of sanitary pads is recommended.

Will I feel Kyleena® during sex?[1]

You and your partner **shouldn't be able to feel your Kyleena® during sex**. If you think you can, contact your doctor or nurse.

Can Kyleena® fall out?[1]

It is possible, but unlikely, for your Kyleena® to come out of place. If you experience pain or an increase in bleeding, use a barrier method of contraception (such as condoms) and book an appointment with your doctor or nurse.

Could I become pregnant using Kyleena®?[1]

Kyleena® is **over 99% effective** for each year of use so you are unlikely to become pregnant while using it. Some women find that their periods change or stop when they use Kyleena®, so missing your period may not actually mean you are pregnant.

If you are worried or experience pregnancy symptoms like feeling sick, tired or having tender breasts, then it's best to see your doctor or nurse as soon as possible.

If you do become pregnant while using Kyleena®, there is a chance that the pregnancy could develop outside of the womb; this is known as an ectopic pregnancy. Some typical symptoms of an ectopic pregnancy include:

- **a missed period followed by persistent bleeding or pain**
- **pain in your lower abdomen that's severe or constant**
- **usual pregnancy symptoms like feeling sick and tired, but you also have bleeding and feel dizzy**
- **a positive pregnancy test[1]**

Can I stop using Kyleena®?[1]

Kyleena® can be removed by a healthcare professional **you can choose to stop using Kyleena® at any time**. Talk to your doctor or nurse and they will arrange for it to be removed.