Kyleena® (levonorgestrel) 19.5 mg intrauterine delivery system
Prescribing Information for United Kingdom

(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: Intrauterine delivery system containing 19.5 mg levonorgestrel. **Indication(s):** Contraception for up to 5 years. **Posology & method of administration:** Before insertion, examine the patient to detect any contraindications, and exclude pregnancy and sexually transmitted diseases. Insert into the uterine cavity within 7 days of onset of menstruation. Consider the possibility of ovulation and conception before use. Delay postpartum insertions until the uterus is fully involuted and at least 6 weeks after delivery (unless involution is substantially delayed, consider waiting until 12 weeks postpartum). Immediate postpartum insertion (IPPI), immediately after placental removal, may be offered only where it is part of locally accepted clinical practice, following an individual benefit-risk assessment, and should be performed by healthcare professionals trained and experienced in IPPI. Where applicable, counsel women prenatally on IPPI availability, the increased risk of expulsion, which may be unnoticed, the need for self-examination after 6–8 weeks & alternative contraceptive methods to ensure informed decision-making. The supplied inserter must not be used for IPPI, as this increases the likelihood of incorrect placement and expulsion. For IPPI, remove Kyleena from the inserter by first loading and then releasing the IUS from the inserter, and insert according to accepted practice and local guidelines; see SmPC for full instructions. Kyleena can be inserted immediately after a first trimester termination. After insertion, women should be re-examined after 4 to 6 weeks to check the threads and ensure that the device is in the correct position. Removal/replacement: Kyleena is removed by gently pulling on the threads with forceps. The use of excessive force/sharp instruments during removal may cause breakage of the system. After removal of Kyleena, the system should be examined to ensure that it is intact and has been completely removed. Kyleena is effective for 5 years; remove after 5 years use – new system can be inserted at the same time. Kyleena is not indicated in postmenopausal women and is not suitable for use as a post-coital contraceptive. Prescribers should consult the SmPC for full information on inserting, removing and replacing Kyleena. ***Hepatic impairment***: Kyleena is contraindicated in women with acute liver disease or liver tumour. ***Renal impairment***: Kyleena has not been studied in women with renal impairment. ***Paediatrics*** – Not indicated before menarche. **Contra-indications:** 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 past 3 months; cervical intraepithelial neoplasia until resolved; uterine or cervical malignancy; progestogen-sensitive tumours, e.g. breast cancer; abnormal vaginal bleeding of unknown aetiology; congenital/acquired uterine anomaly including fibroids which would interfere with insertion and / or retention of the system (i.e. if they distort the uterine cavity); acute liver disease or liver tumour; hypersensitivity to the active substance or excipients. **Warnings & precautions:** Use with caution after specialist consultation & consider removal if the following 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 of blood pressure; severe arterial disease such as stroke or myocardial infarction. Monitor blood glucose in diabetic users. Inform patient of benefits/risks including signs & symptoms of perforation & risk of ectopic pregnancy. Emphasis should be given to training in the correct insertion technique. Insertion/removal may be associated with pain & bleeding & may result in a vasovagal reaction (e.g. syncope, or a seizure in an epileptic patient). Not recommended for the treatment of heavy menstrual bleeding or protection from endometrial hyperplasia. If a woman becomes pregnant while using Kyleena, the relative likelihood of this pregnancy being ectopic is increased. 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. Consider ectopic pregnancy if lower abdominal pain occurs, especially with missed periods or if an amenorrhoeic woman starts bleeding –higher risk of ectopic pregnancy for women with previous history of ectopic pregnancy, tubal surgery or pelvic infection. Ectopic pregnancy may impact future fertility so benefits and risk of use should be carefully evaluated on an individual woman basis. Irregular bleeding and spotting are common in first months of use. Thereafter, reduction of duration & volume of menstrual bleeding occur as a result of endometrium suppressions. If bleeding becomes heavier and/or more irregular over time use appropriate diagnostic measures as irregular bleeding may be a symptom of endometrial polyps, hyperplasia or cancer & heavy bleeding may be a sign of unnoticed expulsion of Kyleena. As with any IUS/IUD, the highest rate of PID was seen during the first 3 weeks after insertion and decreases thereafter. Although extremely rare, severe infection or sepsis (including group A streptococcal sepsis) can occur following Kyleena insertion. Kyleena must be removed if a woman experiences recurrent endometritis or PID or if an acute infection is severe or does not respond to treatment. Bacterial examinations & monitoring are recommended even with discrete symptoms indicative of infections. Bleeding, pain or increased menstrual flow may indicate partial/complete expulsion. Immediately exclude perforation of uterus or cervix in cases of difficult insertion and/or exceptional pain/bleeding during or after insertion e.g. physical examination and ultrasound. Such a system must be removed; surgery may be required. Risk of perforation is increased in breast-feeding women, insertions up to 36 weeks post- partum & in women with fixed retroverted uterus. The insertion instructions and the inserter provided with Kyleena are not applicable for IPPI. Prescribers should consult the SmPC for further guidance on infection, expulsion, or perforation. Breast cancer: The diagnostic risk in users of progestogen-only methods (POPs, implants and injectables) is possibly of similar magnitude to that associated with COC. Observational studies of levonorgestrel IUS users versus non-users or non-hormonal users show inconsistent breast cancer risk findings, with evidence less conclusive than for COCs. Advise women to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating treatment. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Precaution at time of removal: The use of excessive force/sharp instruments during removal may cause breakage of the system. After removal of Kyleena, the system should be examined to ensure that it is intact and has been completely removed. **Fertility, Pregnancy & breast-feeding:** *Fertility:* Use of Kyleena does not alter the course of future fertility. Upon removal of Kyleena, women return to their normal fertility. *Pregnancy:* If pregnancy occurs with Kyleena in situ, exclude ectopic pregnancy and remove system. Removal of Kyleena or probing of uterus may result in spontaneous abortion. If woman wishes to continue pregnancy and system cannot be removed, inform her about risks and possible consequences of premature birth to the infant. Monitor pregnancy closely. Instruct woman to report all symptoms suggesting complications of the pregnancy, like cramping abdominal pain with fever. There have been isolated cases of masculinisation of the external genitalia of the female foetus following local exposure to levonorgestrel during pregnancy with an LNG-IUS in place. *Breast-feeding*: About 0.1% of the levonorgestrel dose passes into the breast milk in nursing mothers but no known deleterious effects on infant growth/development. **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; this is *very common* when insertion is performed immediately postpartum), genital discharge, increased weight. *Serious: cf. CI/Warnings and Precautions - in addition:* hypersensitivity (incl. urticaria, angioedema). Cases of sepsis (incl. group A streptococcal sepsis) have been reported following IUD insertion. A large post authorisation safety study shows an increased risk of perforation in breast-feeding women or insertions up to 36 weeks post-partum. Prescribers should consult the SmPC in relation to other side effects. **Legal Category:** POM. **Package Quantities and Basic NHS Costs:** £76.00 **MA Number(s):** PL 00010/0664. **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** October 2026

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Reporting adverse events and quality complaints

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Email: pvuk@bayer.com

Please report information of when Kyleena was inserted and removed, as applicable.