An mbeidh tionchar ag Kyleena® ar mo thorthúlacht?[1]

Tá Kyleena® inchúlaithe go hiomlán. Ciallaíonn sé sin go bhfillfidh do ghnáthleibhéal torthúlachta tar éis Kyleena® abhaint. Is féidir Kyleena® a bhaint ag am ar bith. Mar sin, má bheartaíonn tú go n-éireoidh tú torrach, is féidir le do ghairmí sláinte Kyleena® a bhaint le linn aon chuairt ghairid amháin. Nuair a bhaintear Kyleena®, is féidir leat iarracht a dhéanamh éirí torrach láithreach.[1]

Cad iad na fo-iarmhairtí a bhaineann le Kyleena®?[1]

Is iondúil go bhfulaingítear Kyleena® go maith, ach de réir mar a théann do chorp i dtaithí air, d'fhéadfaí go mbeadh ann roinnt fho-iarmhairtí. Is iad seo a leanas cuid de na fo-iarmhairtí coitianta a d'fhéadfaí go mbeifeá thíos leo, tinneas cinn, aicne/craiceann bealaithe,athruithe i dtaca le fuiliú, pian abdómain, cist ubhagánach. De réir mar théann do chorp i dtaithí ar an Kyleena® is iondúil go n-imíonn na fo-iarmhairtí seo.
Labhair le do ghairmí sláinte le do thoil, má tá aon imní ort i dtaca le fo-iarmhairtí féideartha.

Cá háit ar féidir liom tuilleadh eolais a fháil?

Tá súil againn go raibh an leabhrán cabhrach. Má tá tuilleadh ceisteanna agat, cuir ar do ghairmí sláinte iad, le do thoil, nó tabhair cuairt ar www.medicines.ie le haghaidh tuilleadh eolais.

Tagairt
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

Bayer Teo.
1 Urlár Oifigí na Gráinsí, An Ghráinseach, Bóthar na Grúdlainne
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PP-PFM-WHC-IE-0029-1 | May 2023

Kyleena®

CÓRAS SEACHADTA IONÚTARACH 19.5MG
LÉABHANOIRGEISTRIL

Treoir le haghaidh do Kyleena®

Irish Leaflet

BAYER

Arna dhéanamh ag Bayer

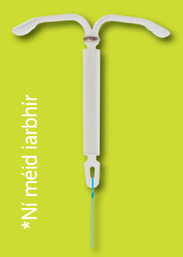
This leaflet is intended for women who have beenprescibed Kyleena®. Léigh an leabhrán i dtaca le heolas othair a chuimsítear i do bhosca Kyleena® le haghaidh na sonraí uile.

Tugadh an leabhrán seo duit toiscgur roghnaigh tú Kyleena®, córas ionútarach beag a shuíonn i do bhroinn chun toircheas a chosc.

Kyleena®:[1]

- **Córas Ionútarach, ar tháirge frithghiniúna buanseasmhach inchúlaithe (LARC) é**
- **Scaoiltear dáileog íseal hormóin leis**
- **Níl aon éastraigin ann**
- **Is féidir úsáid a bhaint as is cuma má shaolaigh tú leanbh nó nár shaolaigh**
- **Oiriúnach do mhná de gach aois a bhfuil táirge frithghiniúna uathu**

Is é seo Kyleena®:[1]



*Ní méid iarbhír

Cruth T beag, solúbtha, plaisteach a shuíonn i do bhroinn. Agus é feistithe, ní cheart go mbeadh a fhios agat fiú go bhfuil sé ann.

Cé chomh héifeachtach is atá Kyleena®?[1]

Tá Kyleena 99% níos éifeachtaí le "úsáid gan locht", rud a chiallaíonn go n-éiríonn níos lú ná aon bhean amháin as gach 100 a bhaineann úsáid as an modh seo ar feadh bliana torrach.

Soláthraítear frithghiniúint éifeachtach le Kyleena® ar feadh suas le 5 bliana, ach féadfar é a bhaint níos luaithe ná sin.

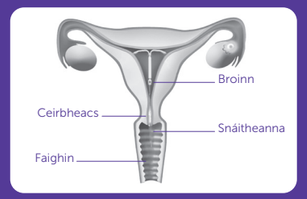
An mbeidh cosaint agam láithreach?[1]

Má chuirtear Kyleena® isteach **faoi cheann 7 lá ó thús d'fhola míosta, cosnófar thú ar thoircheas** láithreach.

Cén chaoi a n-oibríonn Kyleena®?[1]

Le Kyleena®, **scaoiltear méid beag hormóin go mall**, próigeistéarón ar a dtugtar léabhanoirgeistril. Ós rud é go gcuirtear Kyleena® isteach sa bhroinn, oibríonn sé san áit ina bhfuil gá leis agus ní thiocfar ach méideanna an-bheag hormóin isteach i sruth d'fhola.

De ghnáth, leantar leis an ubhsceitheadh (scaoileadh uibhe ó na hubhagáin) agus Kyleena á úsáid®.



Cuirtear cosc ar thoircheas le Kyleena®trí:[1]

- **múcas do cheirbheacs a thiúchan, lena gcuirtear cosc ar an síol a dhul tríd chun ubh a thoirchiú**
- **líneáil do bhroinne a thanú, lena gcruthaítear deacrachtaí don ubh a ghreamú léi**

Cad a tharlaíonn ag do choinne feistithe?[1]

Ní cheart go mbeadh níos mó ná cúpla nóiméad i gceist le Kyleena® a chur in áit, ach beidh coinne níos faide agat ionas gur féidir le do dhochtúir nó le d'altra gach rud a phlé leat, chun a chinntiú nach bhfuil tú torrach agus le bheith cinnte go bhfuil tú sásta leanúint ar aghaidh.

Nuair atá tú compordach agus réidh, cuirtear Kyleena® isteach sa bhroinn trí úsáid a bhaint as tiúb thanaí.

Cuirfidh do dhochtúir nó d'altra ar an eolas thú faoin gcaoi a seiceáiltear go bhfuil do Kyleena® in áit trí na snáitheanna a aimsiú agus do lámh a chur orthu.

An mbeidh sé pianmhar?[1]

D'fhéadfaí go mbeifeá thíos le pian agus/nó meadhrán le linn nó i ndiaidh feistithe a shuaimhníonn go tapa de ghnáth. Má tá faoiseamh ó phian uait sula gcuirtear Kyleena® isteach, labhair le do ghairmí sláinte, le do thoil, faoichóir leighis coisctheach dírithe ar fhaoiseamh ó phian. Tar éis é a chur isteach, d'fhéadfaí go mbeifeá thíos le pian éigin, amhail crampaí míosta. Imíonn sé seo tar éis cúpla lá de ghnáth, áfach. Má tá tú thíos le pian thromchúiseach nó má tá tú ag cur fola go trom tar éis an Kyleena® a chur isteach nó má leanfar leis an bpian/fuiliú ar feadh níos mó ná cúpla seachtain, déan coinne le do ghairmí sláinte, le do thoil

Agus é feistithe, **ní chóir go mbeifeá in ann do Kyleena® a mhothú.**

Cad é a tharlaíonn ina dhiaidh sin?[1]

Tar éis é a chur isteach, d'fhéadfaí go mhothófá pian ar nós crampaí míosta. Imíonn sé seo tar éis cúpla lá de ghnáth, áfach. Má tá tú thíos le pian thromchúiseach nó má tá tú ag cur fola go trom tar éis Kyleena® a chur isteach, nó má leanfar leis an bpian nó an bhfuiliú ar feadh níos mó ná cúplaseachtain, déan coinne le do dhochtúir nó le d'altra, le do thoil.

Ba cheart go sholáthrófaí scrúdú sláinte duit 4-6 seachtaine tar éis duit é a chur isteach le cinntiú go bhfuil gach rud ag éirí go maith.

Ag deireadh na cúigiú bliana, ba cheart go mbainfeadh do dhochtúir nó d'altra do Kyleena®. Más mian leat leanúint ort ag baint úsáid as Kyleena®, is féidir leat ceann nua a fháil le linn na coinne céanna.

An dtiocfaidh athrú ar m'fhuil mhíosta?[1]

Ní hionann gach bean, ach is dócha go mbeidh tionchar ag Kyleena® ar do thimthriall míosta, go háirithe le linn na chéad 3-6 mhí tar éis é a chur in áit. D'fhéadfaí go mbeadh breacadh agus fuiliú idir do ghnáth fuil mhíosta i gceist leis an bhfuiliú a d'fhéadfadh tarlú le linn do do bhroinn a dhul i dtaithí ar Kyleena®.

Cúpla mhí ina dhiaidh seo, áfach, **d'fhéadfaí go n-éireodh d'fhuil mhíosta níos éadroime, níos gairide nó má chuireann deireadh iomlán léi**. Is gnáthrud é seo.

An féidir liom súitíní a úsáid fós?[1]

Sea, ós rud é go suíonn Kyleena® i do bhroinn seachas i d'fhaighin, is féidir leat leanúint ar aghaidh ag baint úsáid as súitíní. Ba cheart duit iad a athrú go cúramach ionas nach dtarraingeoidh tú snáitheanna an Kyleena®. Moltar úsáid a bhaint as pillíní sláintíocha.

An mothóidh mé Kyleena® le linn collaíochta?[1]

Ní chóir go mbeadh tusa nó do pháirtí **in ann an Kyleena® a mhothú le linn collaíochta**. Má cheapann tú gur féidir leat, déan teagmháil le do dhochtúir nó le d'altra.

An bhféadfar go dtitfidh Kyleena® amach?[1]

Is féidir, ach is beag an seans é, go dtitfeadh do Kyleena® amach as áit. Má thagann pian nó méadú fuilithe ort, bain úsáid as modh bacainneach frithghiniúna (amhail coiscíní) agus cuir coinne in áirithe le do dhochtúir nó le d'altra.

An bhféadfaí go n-éireoinn torrach agus Kyleena® á úsáid agam?[1]

Tá éifeachtúlacht ós cionn 99% ag Kyleena®le haghaidh gach bliain úsáide agus mar sin ní dócha é go n-éireoidh tú torrach agus tú á úsáid. Aithníonn roinnt ban go cuireann deireadh lena míostrú nó go n-athraíonn sé nuair a bhaineann siad úsáid as Kyleena®, mar sin d'fhéadfaí nach mbeadh toircheas mar chúis le d'fhuil mhíosta a chailleadh.

Má tá imní ort nó má tá comharthaí toirchis ort amhail tinneas nó tuirse nó má tá do chíocha goilliúnach, is fearr do dhochtúir nó d'altra a fheiceáil chomh luath agus is féidir.

Má éiríonn tú torrach agus Kyleena® á úsáid agat, d'fhéadfaí go bhforbrófaí an toircheas lasmuigh den bhroinn; tugtar toircheas eachtópach air seo. I measc na ngnáthchomharthaí a bhaineann le toircheas eachtópach tá:

- **fuil mhíosta a cailleadh le fuiliú leanúnach nó pian ina dhiaidh**
- **pian thromchúiseach nó seasmhach in íochtar d'abdómain**
- **gnáthchomharthaí toirchis amhail tuirse nó tinneas a bheith ort, ach tá tú ag cur fola freisin agus tá meadhrán i do cheann**
- **tástáil toirchis dhearfach [1]**

An féidir liom éirí as Kyleena® a úsáid?[1]

Is féidir le gairmí sláinte Kyleena® a bhaint ag am ar bith, is féidir **leat éirí as Kyleena® a úsáid ag am ar bith.** Labhair le do dhochtúir nó le d'altra agus socróidh siad duit go mbainfear é.