Agenda

Women's Health Matters Webinar:

What's new, what's important in Heavy Menstrual Bleeding and Menopause

Wednesday 14th October 2020

7:00pm – 8:30pm

This promotional webinar is part of the Women's Health Matters Educational Programme that is organised and fully funded by Bayer.

Time	Session	Speaker
19:00	**Welcome and introductions**	**Dr Diana Mansour** Consultant in Community Gynaecology and Reproductive Healthcare, Newcastle Hospitals
19:05	**Heavy Menstrual Bleeding**	**Dr Sarah Gray** GP specialist in Women's Health, Cornwall
19:30	**Menopause and Hormone Replacement Therapy (HRT)**	**Dr Diana Mansour** Consultant in Community Gynaecology and Reproductive Healthcare, Newcastle Hospitals
20:00	**Open discussion session – ask the experts** • Your questions answered	**Dr Diana Mansour** **Dr Sarah Gray**
20:30	***Close***	

To register please click https://whm.e4h.co.uk/

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk

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Prescribing Information is on the reverse and will also be available during the webinar

Mirena® (levonorgestrel) 20 micrograms/24 hours intrauterine delivery system Prescribing Information

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

Presentation: Intrauterine system consisting of T-shaped frame containing 52mg levonorgestrel. **Indication(s):** Contraception, idiopathic menorrhagia, protection from endometrial hyperplasia during oestrogen replacement therapy. **Posology & method of administration**: Before insertion exclude pregnancy & genital infection. Contraception, idiopathic menorrhagia: Women of fertile age: insert into uterine cavity within 7 days of onset of menstruation. Delay postpartum insertions until 6 weeks after delivery. Mirena can be inserted immediately after a first trimester termination. Mirena is effective for 5 years; remove after 5 years use - new system can be inserted at the same time.

Protection from endometrial hyperplasia during oestrogen replacement therapy: Insert at any time in an amenorrhoeic woman or during last days of menstruation or withdrawal bleeding - remove after 4 years. In women receiving HRT, Mirena can be used with unopposed oestrogens. Prescribers should consult the SmPC for full information on inserting & removing Mirena.

Contra-indications: Known/suspected pregnancy; confirmed/suspected hormone dependent tumours (incl. breast cancer); (re-)current pelvic inflammatory disease (PID); cervicitis; current genital infection; postpartum endometritis, infected abortion during past 3 months; increased susceptibility to infections; cervical dysplasia; uterine/cervical malignancy; undiagnosed abnormal genital bleeding; congenital/acquired uterine abnormality incl. fibroids that distort the uterine cavity; liver tumour or other acute/severe liver disease; acute malignancies affecting the blood or leukaemias except when in remission; recent trophoblastic disease with elevated hCGlevels; hypersensitivity to the active substance or excipients. Active/previous severe arterial disease (e.g. stroke or MI), when used with concomitant oestrogen for HRT use.

Warnings & precautions: Use with caution & consider removal if the following exist or occur for the first time: Migraine with aura, unusually severe or frequent headache, jaundice, marked increase of blood pressure, malignancies affecting the blood or leukaemias in remission, use of chronic corticosteroid therapy, history of ovarian cysts, active/previous severe arterial disease, severe/multiple risk factors for arterial disease, thrombotic arterial or any current embolic disease, acute VTE.

Use with caution in postmenopausal women with advanced uterine atrophy. Insertion technique is different from other intrauterine devices (IUDs); special emphasis should be given to training in the correct insertion technique. Insertion/removal may be associated with pain & bleeding & may result in fainting as a vasovagal reaction or seizure in epileptics. In cases of difficult insertion, exceptional pain/bleeding during or after insertion, exclude perforation of uterus or cervix– physical examination may not be sufficient. If perforation suspected, remove system; surgery may be required. Risk of perforation is increased in breastfeeding women, insertions up to 36 weeks post-partum& in women with fixed retroverted uterus. The Mirena inserter has been designed to minimise the risk of infections. In users of copper IUDs, the highest rate of pelvic infections occurs during the first month after insertion & decreases later. Although extremely rare, severe infection or sepsis (including group A streptococcal sepsis) can occur following IUS insertion. If pelvic infection suspected bacteriological examinations & monitoring is recommended, even with discrete symptoms. Start appropriate antibiotics & remove Mirena if symptoms do not resolve within 72hrs, if recurrent endometritis or pelvic infection occurs, or if an acute infection is severe. Bleeding, pain, increased menstrual flow may indicate partial/complete expulsion. Prescribers should consult the SmPC for further guidance on perforation, infection or expulsion. Reduction in menorrhagia is usually achieved in 3 to 6 months of treatment. If menorrhagia persists: re-examine & consider alternative treatments. Exclude endometrial pathology before insertion. If bleeding irregularities develop during prolonged treatment use appropriate diagnostic measures, as irregular bleeding may mask symptoms/signs of endometrial polyps or cancer. Consider ectopic pregnancy if lower abdominal pain occurs, especially if period is missed or if an amenorrhoeic woman starts bleeding - higher risk of further ectopic pregnancy if previous history exists. Ovarian cysts were reported. Some studies suggest slightly increased risk of breast cancer in women using COCs – may be of similar magnitude for progestogen- only contraception (like Mirena) but evidence is based on smaller no. of users, so is less conclusive than that for COCs. Risk of breast cancer when Mirena used as progestogen component of HRT unknown. See SmPC for full details. 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. Monitor blood glucose in diabetic users. Not suitable for use as a post-coital contraceptive.

Fertility, pregnancy & lactation: Pregnancy: If pregnancy occurs with Mirena in situ, exclude ectopic pregnancy, remove system& consider termination of pregnancy. Removal of Mirena or probing of uterus may result in spontaneous abortion. If removal impossible, inform woman about increased risk of spontaneous abortion/premature labour.

Monitor pregnancy closely. Teratogenicity (esp. virilisation) cannot be excluded, no evidence of birth defects to date. Lactation: About 0.1% of the levonorgestrel dose is transferred during breastfeeding but no known deleterious effects on infant growth/development. Uterine bleeding has been reported rarely during lactation. Fertility: pregnancy rate at 1 year similar to those not using contraception once Mirena is removed for planned pregnancy.

Undesirable effects: Very Common - uterine/vaginal bleeding (incl. spotting), oligomenorrhoea, amenorrhoea Common- depressed mood/depression, nervousness, decreased libido, headache, migraine, dizziness, abdominal pain, nausea, acne, hirsutism, back pain, ovarian cysts, pelvic pain, dysmenorrhoea, vaginal discharge, vulvovaginitis, breast tenderness, breast pain, IUS expulsion, weight increase. Serious side effects - cf. CI/Warnings & Precautions in addition: hypersensitivity (incl. urticaria, angioedema), PID, endometritis, cervicitis. 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 breastfeeding 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 & Basic NHS Costs:** £88.00 **MA Number(s):** PL 00010/0547 **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD, U.K. Telephone: 0118 206 3000. **Date of preparation:** May 2020

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

(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 exclude pregnancy and sexually transmitted diseases. Insert into the uterine cavity within 7 days of onset of menstruation. Delay postpartum insertions until the uterus is fully involuted and at least 6 weeks after delivery. Kyleena can be inserted immediately after a first trimester termination. 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. ***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 etiology; 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. 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. Prescribers should consult the SmPC for further guidance on infection, expulsion or perforation. Ovarian cysts were reported. 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. **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. Virilisation effects in female foetus cannot be excluded. There is no evidence of birth defects to date. *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), 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:** July 2020

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