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 hCG levels; 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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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.

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