▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SPC for how to report adverse reactions.

Jaydess 13.5 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 (13.5mg 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 3 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 Jaydess insertion procedure. Follow full instructions for preparation for insertion, insertion and removal/replacement, particularly with regard to timing and positioning. Jaydess can be distinguished from other IUSs by the visibility of the silver ring on ultrasound. The T-frame of Jaydess contains barium sulphate which makes it visible in X-ray examination. The system should be removed no later than by the end of the third 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. If the system is removed at some other time during the cycle and the woman has had intercourse within a week, she is at risk of pregnancy unless a new system is inserted immediately following removal. After removal of Jaydess, the system should be examined to ensure that it is intact. Elderly patients: Jaydess has not been studied in women over the age of 65 years. There is no indication for the use of Jaydess 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 uterine 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 LNG IUS. Medical examination/consultation: Before insertion, a woman must be informed of the benefits and risks of Jaydess, including the signs and symptoms of perforation and the risk of ectopic pregnancy, see below. A physical examination including pelvic examination and examination of the breasts should be conducted. Cervical smear should be performed as needed, according to healthcare professional's evaluation. 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 Jaydess 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. Jaydess is not for use as a post-coital contraceptive. The use of Jaydess 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 Jaydess was approximately 0.11 per 100 woman-years. Approximately half of the pregnancies that occur during Jaydess use are likely to be ectopic. For women who become pregnant while using Jaydess, 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 Jaydess should be carefully evaluated, in particular for nulliparous women. Use in nulliparous women: Jaydess is not first choice for contraception in nulliparous women as clinical experience is limited. Effects on the menstrual bleeding pattern: Effects on the menstrual bleeding pattern are expected in most users of Jaydess. 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 Jaydess use. Before electing use of Jaydess, 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, Jaydess must be removed. Expulsion: In clinical trials with Jaydess, the incidence of expulsion was low and in the same range as that reported for other IUDs and IUSs. Symptoms of the partial or complete expulsion of Jaydess may include bleeding or pain. However, partial or complete expulsion can occur without the woman noticing it, leading to decrease or loss of contraceptive protection. As Jaydess typically decreases menstrual bleeding over time, an increase of menstrual bleeding may be indicative of an expulsion. A partially expelled Jaydess should be removed. A new system can be inserted at that time provided pregnancy has been excluded. A woman should be advised how to check the threads of Jaydess and to contact her healthcare provider if the threads cannot be felt. 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 Jaydess. In case of a difficult insertion and/or exceptional pain or bleeding during or after insertion, appropriate steps should be taken immediately to exclude perforation, 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. In a large prospective comparative non-interventional cohort study in users of other IUDs (N=61,448 women) with a one-year observation period, the incidence of perforation was 1.3 (95% CI: 1.1 - 1.6) per 1000 insertions in the entire study cohort; 1.4 (95% CI: 1.1 - 1.8) per 1000 insertions in the cohort of another LNG- IUS and 1.1 (95% CI: 0.7 - 1.6) per 1000 insertions in the copper IUD cohort. The study 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. 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 Jaydess. 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 13.2 % of women using Jaydess 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. 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. Advise women to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment. **Interactions:** Interactions can occur with drugs that induce hepatic microsomal enzymes which can result in increased or decreased clearance of sex hormones. Substances that increase the clearance of levonorgestrel include phenytoin, carbamazepine and barbiturates as well as others. The influence of these drugs on the contraceptive efficacy of Jaydess is not known. Substances decreasing the clearance of levonorgestrel include azole antifungals (e.g. fluconazole, itraconazole, ketoconazole,), verapamil, macrolides (e.g. clarithromycin, erythromycin), diltiazem and grapefruit juice can increase plasma concentrations of the progestin. Magnetic resonance imaging (MRI): Non-clinical testing has demonstrated that a patient can be scanned safely after placement of Jaydess under the following conditions: Static magnetic field of 3-Tesla or less, maximum spatial gradient magnetic field of 720-Gauss/cm or less. **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 insertion of Jaydess in pregnant women is contraindicated. If a woman becomes pregnant while using Jaydess ectopic pregnancy should be excluded and timely removal of the system is recommended since any intrauterine contraceptive left in situ may increase the risk of abortion and preterm labour. Removal of Jaydess or probing of the uterus may also result in spontaneous abortion. Clinical experience of the outcomes of pregnancies under Jaydess 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**: Not known. **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, nausea, alopecia, upper genital tract infection, dysmenorrhea, breast pain/discomfort, device expulsion (complete and partial), genital discharge, increased weight; Uncommon: dizziness, hirsutism, uterine perforation. **Marketing Authorisation Number: PA 1410/68/1**. **Marketing Authorisation Holder/ Further information available from**: Bayer Limited, The Atrium, Blackthorn Road, Dublin 18. Tel.: (01) 2163300. **Classification for sale or supply**: prescription only. **Date of preparation:** July 2020.