NUVARING ®
(Etonogestrel/ethinylestradiol)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 01992 467272). By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
Vaginal delivery system containing 11.7 mg etonogestrel and 2.7 mg ethinylestradiol. The ring releases etonogestrel and ethinylestradiol at an average amount of 0.120 mg and 0.015 mg respectively per 24 hours, over a period of 3 weeks.

USES
Contraception.
Decision to prescribe based on individual woman's risk factors, particularly those for venous thromboembolism (VTE).

DOSAGE AND ADMINISTRATION
See SmPC for full details. Use as directed to achieve contraceptive effectiveness. The woman herself can insert NuvaRing in the vagina. Advise the woman how to insert and remove the ring. Following insertion, the woman is to leave the ring in the vagina continuously for 3 weeks. Advise the woman to regularly check for the presence of the ring in the vagina, especially before and after intercourse. If expelled, the woman should follow the instructions in the Package Leaflet. The woman must remove the ring after 3 weeks of use on the same day of the week as the ring was inserted. The woman is to insert a new ring after a ring-free interval of 1 week. Do not use other female barrier methods (such as diaphragm, cervical cap, or female condom) as back-up methods.

Paediatric population: safety and efficacy < 18 years old not studied. Refer to SmPC for initiation, switching advice, management of ring-free interval and lengthened ring-use.

Applicator not available in the UK.

CONTRA-INDICATIONS
Do not use combined hormonal contraceptives (CHCs) in the following conditions: history of, presence of (including with anticoagulant use), known hereditary or acquired predisposition of, or risk of VTE; major surgery with prolonged immobilisation; known hereditary or acquired predisposition for, history of, presence of or risk of arterial thromboembolism (ATE) or prodromal condition; cerebrovascular disease; migraine with focal neurological symptoms; high risk of ATE due to multiple risk factors such as diabetes mellitus with vascular symptoms, severe hypertension and severe dyslipoproteinaemia; pancreatitis or a history thereof if associated with severe hypertriglyceridemia; presence or history of severe hepatic disease unless liver function values return to normal; presence or history of liver tumours; known or suspected malignant conditions of the genital organs or the breasts (if sex steroid-influenced), undiagnosed vaginal bleeding, hypersensitivity to the active substances or to any of the excipients. Co-administration with ombitasvir, paritaprevir, ritonavir and dasabuvir.

PRECAUTIONS
See SmPC for full details. **Circulatory disorders**: VTE: The use of any CHCs increases the risk of VTE compared with no use. NuvaRing may have up to twice the level of risk compared with products that contain levonorgestrel, norgestimate or norethisterone which are associated with the lowest risk of VTE. The decision to use any product other than one with the lowest VTE risk should be taken only after a discussion with the woman to ensure she understands the risk of VTE with NuvaRing, how her current risk factors influence this risk, and that her VTE risk is highest in the first ever year of use. An increased risk when a CHC is re-started after a break in use of 4 weeks or more has also been established. ATE: Epidemiological studies have associated the use of CHCs with an increased risk for ATE or for cerebrovascular accident. In the event of VTE/ATE symptoms urgent medical attention should be sought and healthcare professional informed of CHC use. An increase in frequency or severity of migraine during CHC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of CHCs. Refer to SmPC for risk factors and signs and symptoms of thrombotic events. **Tumours**: increased risk of cervical cancer in long-term users of oral contraceptives reported in some studies, but may be due to effects of sexual behaviour and other

factors such as human papilloma virus. No epidemiological data on the risk of cervical cancer in users of NuvaRing are available. In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of combined oral contraceptives (COCs). **Other conditions**: Women with hypertriglyceridemia, or a family history thereof, may be at an increased risk of pancreatitis when using hormonal contraceptives. If a sustained clinically significant hypertension develops during the use of NuvaRing, suspend the use of the ring and treat the hypertension. NuvaRing use can be resumed if normotensive values can be achieved with antihypertensives. Jaundice and/or pruritus related to cholestasis, gallstone formation, porphyria, systemic lupus erythematosus, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis and otosclerosis-related hearing loss have been reported to occur/deteriorate with pregnancy and use of hormonal contraceptives. Exogenous oestrogens may induce or exacerbate symptoms of (hereditary) angioedema. Acute or chronic disturbances of liver function may necessitate discontinuation of use of the ring until markers return to normal. Diabetic women should be carefully observed while using the ring. Crohn's disease and ulcerative colitis have been associated with the use of hormonal contraceptives. Chloasma may occasionally occur. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst using the ring. If a woman has any of the following conditions she may not be able to insert the ring correctly or may in fact lose the ring: prolapse of the uterine cervix, cystocele and/or rectocele, severe or chronic constipation. During the use of NuvaRing, women may occasionally experience vaginitis. There are no indications that the efficacy of NuvaRing is affected by the treatment of vaginitis, or that the use of NuvaRing affects the treatment of vaginitis. NuvaRing has been reported to adhere to the vaginal tissue. In some cases, when the tissue had grown over the ring, removal was achieved by cutting the ring without incising the overlying vaginal tissue. Depressed mood and depression can be associated with hormonal contraceptive use. Depression can be a risk factor for suicidal behaviour and suicide. Advise women to contact their physician if they develop mood changes and depressive symptoms. **Broken rings**: The product may get disconnected during use. Vaginal injury associated with ring breakage has been reported. Women are advised to remove the broken ring and reinsert a new ring as soon as possible and use a barrier method for the next 7 days. **Expulsion**: NuvaRing has been reported to get expelled if not inserted properly, while removing a tampon, during sexual intercourse, or in case of severe or chronic constipation. To ensure efficacy, the woman should be advised to regularly verify the presence of the ring. The possibility of a pregnancy should be considered and the woman should contact her physician.

Drug interactions: Interactions can occur with other drugs which may lead to breakthrough bleeding and/or contraceptive failure. Interactions can occur with medicinal or herbal products that induce microsomal enzymes, specifically cytochrome P450 enzymes (CYP) (e.g. phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir), non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz) and products containing St. John's wort). Co-administration with combinations of HIV protease inhibitors (e.g., nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine), and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g., boceprevir, telaprevir), can increase or decrease plasma concentrations of progestagens including etonogestrel. Concomitant use of strong or moderate CYP3A4 inhibitors may increase serum concentrations. Refer to SmPC for advice on additional contraceptive requirements. The prescribing information of concomitant medications should be consulted to identify potential interactions.

Pregnancy and Lactation: Do not use during pregnancy. If pregnancy occurs during use, the ring should be removed. The use of NuvaRing is not recommended until the nursing mother has completely weaned her baby.

SIDE EFFECTS

Refer to Summary of Product Characteristics for complete information on side-effects.

The most common adverse reactions reported (rate > 1/100 to < 1/10) are: vaginal infection, depression, decrease in libido, headache, migraine, abdominal pain, nausea and acne.

Serious side effects reported include:

Rare (≥ 1/10,000 to < 1/1,000): Venous thromboembolism and arterial thromboembolism.

Frequency not known: hypersensitivity reactions, including angioedema and anaphylaxis.

PACKAGE QUANTITIES AND BASIC NHS COST

3 sachets containing 1 ring - £29.70

Marketing Authorisation number

PL 00025/0565

Marketing Authorisation Holder: Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, UK

Legal category: POM

Date of review of prescribing information: December 2019

PI.NVRNG.19.UK.7078.WS-257