EVRA® 203 micrograms/24 hours + 33.9 micrograms/24 hours transdermal patch

PRESCRIBING INFORMATION

ACTIVE INGREDIENT(S): Norelgestromin (NGMN) and ethinyl estradiol (EE).

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

INDICATION(S): Female contraception, intended for women of fertile age. Safety/efficacy established in women aged 18-45 years. The decision to prescribe EVRA should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with EVRA compares with other CHCs (see contraindications and special warning and precautions).

DOSAGE & ADMINISTRATION: Adults: Transdermal use. One patch for 7 days, for 3 weeks followed by 1 week patch free. See SmPC for full details of administration. No data in women >45 years of age. Contraceptive efficacy in women ≥ 90kg may be reduced. Under no circumstances should there be more than a 7-day transdermal patch-free interval between dosing cycles. If there are more than 7 transdermal patch-free days, the user may not be protected against pregnancy. A non-hormonal contraceptive must then be used concurrently for 7 days. **Post-menopausal women:** not indicated for post-menopausal women and is not intended for use as hormonal replacement therapy. **Children**: Not recommended < 18 years of age. **Renal impairment**: not studied but supervision required. **Hepatic impairment:** Not studied – see contraindications.

CONTRAINDICATIONS: Presence or risk of VTE: Current VTE requiring anticoagulant therapy, history of deep vein thrombosis (DVT), or pulmonary embolism. Known hereditary or acquired risk of VTE. Major surgery with prolonged immobilisation. A high risk of venous thromboembolism due to the presence of multiple risk factors. **Presence or risk of ATE:** Arterial thromboembolism – current, history of, or prodromal condition (e.g. angina pectoris). Cerebrovascular disease – current stroke, history of stroke or prodromal condition (e.g. transient ischaemic attack. Known hereditary or acquired predisposition for arterial thromboembolism. History of migraine with focal neurological symptoms. A high risk of ATE due to multiple risk factors or to the presence of one serious risk factor such as diabetes with vascular symptoms, severe hypertension, severe dyslipoproteinaemia. **Other contraindications:** Hypersensitivity to active substances or excipients. Known or suspected carcinoma breast, endometrium or other oestrogen-dependent neoplasia. Hepatic adenomas or carcinoma. Abnormal liver function related to acute or chronic hepatocellular disease. Undiagnosed abnormal genital bleeding. Drug combinations with paritaprevir/ritonavir, ombitasvir, and/or dasabuvir.

SPECIAL WARNINGS & PRECAUTIONS: If any of the conditions/risk factors mentioned below is present, the suitability of EVRA should be discussed with the woman. In the event of aggravation, or first appearance of any of the conditions or risk factors, the woman should be advised to contact her doctor to determine whether the use of EVRA should be discontinued. **Risk of VTE:** The use of any CHC increases the risk of VTE compared with no use. Products that contain levonorgestrel, norgestimate or norethisterone are associated with the lowest risk of VTE. Other products such as EVRA may have up to twice this level of risk. 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 EVRA, how her current risk factors influence this risk, and that her VTE risk is highest in the first ever year of use. There is also some evidence that the risk is increased when a CHC is re-started after a break in use of 4 weeks or more. See SmPC for full details. **Risk of ATE:** epidemiological studies have associated the use of CHCs with an increased risk for ATE (myocardial

infarction) or for cerebrovascular accident (e.g. transient ischaemic attack, stroke). Arterial thromboembolic events may be fatal. See SmPC for full details. As with all combined hormonal contraceptives: increased risk of cervical, breast and liver cancer, worsening depression and risk of suicidal behaviour/suicide (women advised to contact physician in case of mood changes), epilepsy, Crohn's disease, ulcerative colitis.

Exclude likelihood of pregnancy before starting treatment. Prior to initiation (and at regular intervals) assess personal and family medical history, measure blood pressure and perform physical examination. Discuss associated risk of VTE/ATE, known personal risk factors and symptoms of VTE and ATE. Increased risk of VTE in 6-week period of puerperium. Instruct to read leaflet carefully. Advise hormonal contraceptives do not protect against HIV infections or sexually transmitted disease. Discontinue: appearance of any contraindication; high blood pressure not responding to treatment; recurrence of cholestatic-related pruritus. Consider discontinuing: aggravation/new risk factors for VTE/ATE; acute/chronic liver function disturbances

Following may occur or deteriorate: jaundice and/or pruritus related to cholestasis, gallbladder disease including cholecystitis and cholelithiasis, porphyria, SLE, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis, otosclerosis-related hearing loss, chloasma. Hepatic tumours reported rarely. Possible increased risk of pancreatitis with hypertriglyceridaemia (including family history). Observe diabetic women carefully. Irregular spotting or bleeding, especially in early treatment. Amenorrhoea/oligomenorrhoea after discontinuation.

SIDE EFFECTS:

Very common: headache, nausea, breast tenderness.
Common: (vulvo) vaginal fungal infection, vaginal candidiasis, mood, affect/anxiety disorders, migraine, dizziness, vomiting, diarrhoea, abdominal pain/distension, acne, rash, pruritus, skin reaction/irritation, muscle spasms, dysmenorrhoea, vaginal bleeding and menstrual disorders, uterine spasm, breast disorders, vaginal discharge, malaise, fatigue, application site reactions (erythema, irritation, pruritus, rash), weight increased.
Other side effects: hepatic neoplasm/adenoma, breast cancer, cervix carcinoma, uterine leiomyoma, fibroadenoma of breast, hypersensitivity, anaphylactic reaction, hypercholesterolaemia, hyperglycaemia/insulin resistance, anger, frustration, libido increased, cerebrovascular accident, cerebral haemorrhage, abnormal taste, arterial thromboembolism, (acute) myocardial infarction, hypertension, hypertensive crisis, thrombosis (arterial/venous/pulmonary), venous thromboembolism, pulmonary embolism, colitis, cholecystitis, cholelithiasis, hepatic lesion, jaundice cholestatic, cholestasis, alopecia, dermatitis allergic, eczema, photosensitivity reaction, dermatitis contact, urticaria, erythema angioedema, erythema (multiforme, nodosum), chloasma, exfoliative rash, pruritus generalised, rash (erythematous, pruritic), seborrhoeic dermatitis, galactorrhoea, premenstrual syndrome, vulvovaginal dryness, cervical dysplasia, suppressed lactation, genital discharge, face oedema, pitting oedema, swelling, application site reactions (e.g., abscess, erosion), localised oedema, blood glucose decreased/abnormal.

LEGAL CATEGORY: POM

Presentations	Pack sizes	MA numbers	Basic NHS costs
Transdermal Patch	9 patches	NI: EU/1/02/223/002 GB: PLGB 04854/0191	£19.51

MARKETING AUTHORISATION HOLDER:

Northern Ireland: Gedeon Richter Plc. Gyömrői út 19-21. 1103 Budapest Hungary
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Great Britain: Gedeon Richter Plc. Gyömrői út 19-21. 1103 Budapest Hungary
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