

Nuvaring® ▼ 0.120 mg/0.015mg per 24 hours vaginal delivery system
Etonogestrel and ethinylestradiol

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics before prescribing.

Presentation: Vaginal ring. **Uses:** Contraception. **Dosage and Administration:** A ring should be inserted into the vagina and left in for 3 weeks. The ring should be removed after 3 weeks. Strictly follow insertion and removal instructions. **Contraindications:** Presence/history of venous thrombosis, with/without the involvement of pulmonary embolism. Presence/history of arterial thrombosis or prodromi of a thrombosis. Known predisposition for venous/arterial thrombosis, with/without hereditary involvement or the presence of severe/multiple risk factors. History of migraine with focal neurological symptoms. Diabetes mellitus with vascular involvement. Pancreatitis or history thereof if associated with severe hypertriglyceridemia. Presence/history of severe hepatic disease if liver function values abnormal. Presence/history of liver tumours. Known/suspected sex-hormone dependent tumours. Undiagnosed vaginal bleeding. Hypersensitivity to any ingredients. **Precautions and Warnings:** No epidemiology data available on vaginal administration but the warnings for combined OCs (COCs) are considered applicable. Use of hormonal contraceptives has been associated with increased risk of venous thromboembolism (VTE, DVT, PE) and arterial thrombosis. It is unclear whether NuvaRing carries the same risk. Remove ring in event of a thrombosis and before long-term immobilisation. Counsel patients on symptoms of thrombosis. Increased risk of cervical cancer in long term COC users infected with human papilloma virus (HPV) has been reported, but this may be confounded by other factors. Risk of breast cancer possibly similar to that associated with COCs. This may be due to earlier diagnosis in COC users, the biological effects of the COC, or a combination of both. Abnormal liver function or liver tumors. Increased risk of pancreatitis in women with hypertriglyceridemia taking hormonal contraceptives. Hypertension. Diabetic women should be carefully monitored. Crohn's disease/ulcerative colitis may deteriorate. Chloasma may occasionally occur. History during pregnancy/previous use of sex steroids: jaundice and/or pruritis related to cholestasis, gallstone formation, porphyria, SLE, HUS, Sydenham's chorea, herpes gestationis, otosclerosis. Remove ring if there is increased frequency/severity of migraine. Increased risk of thromboembolism in the puerperium. May not be suitable for women with a prolapse or severe constipation. Consider incorrect positioning in case of cystitis. Occasional vaginitis. If ring adheres to vaginal tissue, removal must be carried out by the healthcare provider. If ring accidentally expelled or broken follow SPC instructions. **Interactions:** Possible interactions with phenytoin, phenobarbital, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, ritonavir, griseofulvin, penicillins, tetracyclines, ciclosporin, lamotrigine and St John's Wort. Use of antimycotic ovules may increase the chance of ring disconnection. **Pregnancy and Lactation:** Not recommended. **Common Undesirable Effects:** Vaginal infection, depression, decreased libido, headache, migraine, abdominal pain, nausea, acne, pelvic pain, breast tenderness, genital pruritis, female dysmenorrhoea, vaginal discharge, weight increased, discomfort, device expulsion. See SPC for full details of other uncommon side effects.

Overdose: No reports of serious effects from overdose. **Legal Category:** Prescription Only Medicine.

Product Licence Number : PL 0065/0393. **Price:** NuvaRing x 3 £.....

Marketing Authorisation Holder: Organon Laboratories Ltd, Cambridge Science Park, Milton Road, Cambridge CB4 0FL, UK.

Product Authorisation Number: PA 61/29/1. **Price:** NuvaRing x 1 €....., NuvaRing x 3 €.....

Product Authorisation Holder: Organon Ireland Limited, a part of Schering-Plough Corporation, P.O. Box 2857, Drynam Road, Swords, Co. Dublin, Ireland.

Please refer to the full SPC text before prescribing this product. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk (UK) and www.imb.ie (Ireland). Adverse events with this product should also be reported to MSD Drug Safety Department on +44 (0)1707 363773

Date of revision of prescribing information: July 2011

Nuvaring/UK-IRL/07-11/05