

PRESCRIBING INFORMATION

Nexplanon[®]▼ (See SPC before Prescribing)

Etonogestrel

Presentation: Preloaded applicator with a radiopaque non-biodegradable implant containing 68mg of etonogestrel. **Uses:** Contraception. Safety and efficacy have been established in women between 18 and 40 years of age. **Dosage and Administration:** One implant should be inserted subdermally after pregnancy has been excluded. Each implant will last for up to 3 years. Nexplanon should only be inserted or removed by HCPs familiar with the insertion and removal technique. Insertion, removal and replacement instructions must be strictly followed. **Contraindications:** Active venous thromboembolic disorder, known or suspected sex-steroid sensitive malignancies, presence/history of severe hepatic disease with current abnormal liver function tests, undiagnosed vaginal bleeding, hypersensitivity to ingredients. **Precautions and Warnings:** Risk of having breast cancer diagnosed in users of progestogen-only preparations is possibly similar to the slightly increased risk associated with combined OCs. This may be due to earlier diagnosis, the biological effects of the OC, or a combination of both. Some epidemiology studies have associated combined OC use with an increased incidence of VTE, DVT and PE. It is unclear whether etonogestrel carries the same risk. Remove implant in the event of a thrombosis and prior to long-term immobilisation. Caution patients with a history of thromboembolic disorders. Abnormal liver function. Hypertension. Diabetes. Chloasma. HCPs may need to consider earlier replacement of the implant in heavier women. Ectopic pregnancy should be ruled out if a woman presents with abdominal pain and amenorrhoea. History during pregnancy or previous use of sex steroids: jaundice and/or pruritis related to cholestasis, gallstone formation, porphyria, SLE, HUS, Sydenham's chorea, herpes gestationis, otosclerosis, **(hereditary) angioedema**. Expulsion may occur if the implant is not inserted correctly or as a consequence of local inflammation. In rare cases the implant may migrate from the insertion site. **Pregnancy and Lactation:** Not indicated during pregnancy. Exclude pregnancy prior to insertion. Nexplanon may be used during lactation, growth and development of the child should be carefully followed. **Interactions:** Possible interactions with phenytoin, phenobarbital, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, ritonavir, nelfinavir, nevirapine, griseofulvin and St John's Wort. Nexplanon may also interfere with the metabolism of other drugs - consult their prescribing information for details. **Undesirable effects: Very Common:** Vaginal Infection, headache, acne, irregular bleeding, weight increase, breast tenderness and pain. **Common:** Alopecia, dizziness, depressed mood, affect lability, nervousness, nausea, flatulence, libido decreased, increased appetite, abdominal pain, ovarian cyst, painful menstruation, flu-like illness, pain, fatigue, weight decrease, insertion site pain or reaction and hot flushes. Other less common and rarely reported side effects are listed in the SPC. **Overdose:** Remove previous implant before inserting a new one. There are no data on overdose with etonogestrel.

Legal Category: POM

Product Licence Number: PL 0065/0161. **Basic NHS Cost:** 1 x implant £

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

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). Adverse events with this product should also be reported to MSD Drug Safety Department on +44 (0)1707 363773

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