

Nexplanon®
Etonogestrel

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) 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 (tel: 01992-467272), UK. By clicking the above link you will leave the MSD website and be taken to the MHRA website.

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 can be left in place for 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.

CONTRA-INDICATIONS

Active venous thromboembolic disorder, known or suspected sex steroid sensitive malignancies, presence/history of liver tumours (benign or malignant), presence/history of severe hepatic disease with current abnormal liver function tests, undiagnosed vaginal bleeding, hypersensitivity to ingredients.

PRECAUTIONS

During the use of combined oral contraceptives (OC), the risk of having breast cancer is slightly increased possibly due to an earlier diagnosis, biological effects of OC or a combination of both. A similar increased risk of breast cancer diagnosis may be seen in users of progestagen only preparations. Epidemiological studies have associated combined OC (oestrogen and progestogen) use with an increased incidence of venous thromboembolism (VTE, DVT and PE) and arterial thromboembolism (ATE, myocardial infarction and ischaemic strokes). Limited epidemiological data do not suggest an increased risk of VTE or ATE in women using the implant; however, there have been

post-marketing reports of VTE and ATE. Assess risk factors, for VTE and ATE. Remove following thrombosis and consider removal with long-term immobilisation. Caution patients with a history of thromboembolic disorders on the possibility of recurrence. Refer to a specialist if acute or chronic disturbances in liver function occur. Discontinue Nexplanon use if sustained hypertension develops or if there is a significant increase in BP which cannot be adequately controlled. Monitor diabetic women during the first months as there may be an effect on peripheral insulin resistance and glucose tolerance. Women with a tendency to chloasma should avoid sun or U.V radiation whilst using Nexplanon. Consider earlier replacement of the implant in heavier women. Ovarian cysts may occur and disappear spontaneously. Exclude ectopic pregnancy in the event of abdominal pain and amenorrhoea. Conditions which have reported during pregnancy and during the use of sex steroids include jaundice and/or pruritis related to cholestasis; gallstone formation; porphyria; SLE; HUS; Sydenham's chorea; herpes gestationis; otosclerosis -related hearing loss and (hereditary) angioedema. Expulsion may occur if the implant is not inserted correctly or with local inflammation. Rarely the implant may migrate from the insertion site possibly due to deep insertions or intravascular insertion. Localisation of the implant may then be more difficult and removal may require a minor surgical procedure with a larger incision or a surgical procedure in an operating theatre.

In cases where the implant has migrated to the pulmonary artery endovascular or surgical procedures may be needed for removal. The release rate of etonogestrel may be slightly increased when an implant is broken or bent "*in situ*". No clinically meaningful effects expected. Broken or bent implants should be removed in their entirety. Changes in the menstrual bleeding pattern are likely.

Drug interactions: The prescribing information of concomitant medications should be consulted to identify potential interactions. Substances that induce microsomal enzymes (e.g: barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, and HIV/HCV medication like ritonavir, efavirenz, boceprevir, nevirapine and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate and products containing the herbal remedy St. John's Wort (*hypericum perforatum*) can reduce the efficacy of hormonal contraceptives.

Concomitant administration of strong (e.g. ketoconazole, itraconazole, clarithromycin) or moderate (e.g. fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestins, including etonogestrel.

Nexplanon may affect the metabolism of other active substances e.g ciclosporin and lamotrigine.

Pregnancy and Lactation: Not indicated during pregnancy. Exclude pregnancy prior to insertion. If pregnancy occurs the implant should be removed. Nexplanon may be used during lactation; growth and development of the child should be carefully followed.

SIDE EFFECTS

Refer to Summary of Product Characteristic for complete information on side effects

Frequencies can be defined as: Common = $\geq 1/100$ < $1/10$; Uncommon = $> 1/1,000$ < $1/100$; Rare = $> 1/10,000$ < $1/1,000$; Very rare = < $1/10,000$; not known=cannot be estimated from the available data.

Very Common: Vaginal infection, headache, acne, irregular menstruation, weight increase, breast tenderness and pain. **Common:** Alopecia, dizziness, depressed mood, affect lability, nervousness, nausea, flatulence, libido decreased, increased appetite, abdominal pain, ovarian cyst, dysmenorrhoea, flu-like illness, pain, fatigue, weight decrease, insertion site pain or reaction and hot flushes. During post marketing surveillance anaphylactic reactions and angioedema have also been reported.

Expulsion or migration of the implant has been reported, including rarely to the chest wall. Rarely implants have been found within the vasculature including the pulmonary artery which may cause chest pain and/or dyspnea or maybe asymptomatic.

Overdose

Remove previous implant before inserting a new one. There are no data on overdose with etonogestrel.

PACKAGE QUANTITIES AND BASIC NHS COST

1 x implant £83.43

Marketing Authorisation number

PL 00025/0563

Marketing Authorisation holder

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POM

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