For UK HCPs only. Prescribing Information and adverse events reporting can be found at the end of this document.
This document is developed by Organon in collaboration with the NTSP (Nexplanon Training Support Programme) Team.

PHARMACY TOOLKIT

PHARMACY REQUIREMENTS FOR IMPLANT FITTING

Before the procedure (setting up)

The pharmacist

You will need to ensure that you have appropriate professional indemnity to cover implant fitting and removal procedures.

In the room

- Room big enough for a bed (need to access top and tail of bed so can access both arms of patient)
- Trolley with a sterile field
- Anaphylaxis and adrenaline for allergic reactions

During the procedure

For the insertion

- Dressing pack (only basic pack required)
- 2ml Syringe
- Green needle
- Lidocaine 1% for injection
- Non latex gloves or sterile gloves if in the pack
- Skin cleaning antiseptic solution/alcohol wipes
- Small mepore or equivalent adhesive dressing
- Nexplanon (FP10)
- Purple lidded sharp box for the disposal of cytotoxic and hormonal drugs

For the removal

- Dressing pack (basic pack required)
- 2ml syringe
- Orange or blue needle
- Lidocaine 1% for injection
- Sterile gloves if not in pack
- Skin cleaning antiseptic solution/alcohol wipes
- Size 11 scalpels
- Steristrips
- Small mepore or equivalent adhesive dressing
- Purple lidded sharp box for the disposal of cytotoxic and hormonal drugs

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Extras (very rarely required)

- Sterile gauze swabs
- One or two pairs of forceps curved
- Bandage if required

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 Organon, UK (Tel: 0208 1593593). By clicking the above link you will leave the 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 overlying the triceps muscle of the non-dominant upper arm. Exclude pregnancy prior to insertion. Each implant can be left in place for 3 years. Broken implants should be removed. Nexplanon should only be inserted or removed by HCPs who have completed training for the use of the Nexplanon applicator and are familiar with the insertion and removal technique. Insertion, removal and replacement instructions must be strictly followed. Videos demonstrating insertion and removal procedures are available at www.nexplanonvideos.eu

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. Advise patients with a history of thromboembolic disorders of the possibility of recurrence. 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.
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. Changes in the menstrual bleeding pattern are likely. 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. Advise patients to seek medical advice if implant cannot be palpated at any time. External forces may cause broken or bent implants, broken implant fragments may migrate. 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 must be removed in their entirety.

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.

Refer to Summary of Product Characteristic for complete information on side effects
Frequencies can be defined as: Very Common (≥1/10); Common = ≥ 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. **Not known:** During post marketing surveillance anaphylactic reactions and angioedema have also been reported.
Insertion of the implant may cause vasovagal reactions (such as hypotension, dizziness, or syncope).
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
Organon Pharma (UK) Limited
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London EC2A 3NP
United Kingdom
Legal Category: POM

SIDE EFFECTS
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