



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 UK sexual health commissioners.

Purpose of this document – The purpose of this pharmacy toolkit document is to introduce this project and to provide additional information and answer any initial questions that the audience might have.

Audience of this document – Local Authorities, LPCs, Commissioners, Pharmacists, GPs, Nurses and other relevant decision makers/professionals.

How to use this document – This pharmacy toolkit document may be downloaded and used “as is”. Any amendments or alterations remain the responsibility of the local area, and Organon will have no editorial control, ownership or oversight.

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 UK sexual health commissioners.

PHARMACY TOOLKIT INFORMATION AND FAQ

Our [insert location] Local Authority has chosen to be part of a national pilot to explore the possibility of contraception including subdermal implants being provided through pharmacies.

INFORMATION

The “implants in pharmacy” project seeks to enable pharmacists to be able to help women make an informed and appropriate choice around their contraception and to provide almost all forms of contraception within a pharmacy setting.

The pharmacies involved in the project will have the option of delivering contraception to the Tier¹ that they feel most comfortable with, with some pharmacists delivering only emergency contraception, a portion of pharmacists delivering user dependent methods or injectable contraception, and then others who are able to deliver the full range of contraception up to and including the subdermal implant (coils are out of scope for this project as it is recognised that this would be much more difficult in a pharmacy setting).

The goal for this project is to improve access to contraception options for women, increasing the choice in terms of where a woman can access her contraception, including the contraceptive implant, Nexplanon (etonogestrol). Nexplanon is indicated for contraception, safety and efficacy have been established in women between 18 and 40 years of age². Community pharmacy aims to offer an accessible and convenient option - bringing contraception closer to home and at a time that may be more suitable to the individual.

FAQ

Why is the “Implants in Pharmacy Project” needed?

Currently, in many parts of the country women are limited in terms of where they can access contraception and particularly Long-Acting Reversible Contraception (LARC) methods, such as the subdermal implant (SDI)³. Women can access LARC at Sexual and Reproductive Health Services however in other settings, for example in General Practice, the availability of LARC methods is not universal. Clinicians must be specifically trained to deliver LARC services and not all GP practices have a suitably trained clinician. This can result in inequalities in terms of choice and access across the country.³ The addition of contraception provision, including implants, in community pharmacy may help address some of these challenges.

How will training be delivered for the “Implants in Pharmacy Project”?

Training will be given for the provision of counselling for contraception and the delivery of all methods of contraception – this will involve a combination of self-learning, virtual teaching and in-person training. For the provision of the implant there is a requirement to complete the following qualifications through the Faculty of Sexual and Reproductive Healthcare (FSRH) for which training will be provided (a full training plan is available separately on request to your local Commissioner or local Organon contact);

- Online Theory Assessment (OTA)
- Letter of Competence Subdermal Contraceptive Implants Techniques Insertion and Removal (LoC SDI-IR)⁴

How long does it take to complete the training for the “Implants in Pharmacy Project”?

A full training plan is available separately on request to your local Commissioner or local Organon contact.

How are Organon going to help?

Pharmacists will be supported through the training requirements of the NHSE community pharmacy contraceptive service as well as the FSRH (Faculty of Sexual and Reproductive Healthcare) training for subdermal implants.^{4,1}

There will be a tiered approach to the delivery of this contraceptive service and pharmacists can choose which level of service they wish to deliver.

- Tier 1 – Ongoing monitoring and supply of repeat oral contraception (OC) prescriptions
- Tier 2 – Initiation of OC via a Patient Group Direction (PGD)
- Tier 3 – Ongoing monitoring and management of repeat long-acting reversible contraception (LARC), excluding intrauterine systems (IUS) and intrauterine devices (IUD)
- Tier 4 – Initiation of LARCs¹

Who are Organon going to help?

We plan to support pharmacists to extend their skill set and enhance their offering whilst contributing to their local population health needs for Sexual and Reproductive Health.

The APPGSRH (All-Party Parliamentary Group on Sexual and Reproductive Health in the UK) 'Women's Lives, Women's Rights: Strengthening access to contraception beyond the pandemic' report (September 2020) supports the concept of initiating a contraception service in pharmacy. The report endorses community pharmacy as a setting for these services.³

"There are opportunities to improve access by making use of technology, better utilising opportunities that exist in pharmacy and post pregnancy settings and ensuring girls and women have appropriate education and information to enable effective and empowered decision making."³

"Community pharmacies are central to local health and wellbeing and many already provide emergency hormonal contraception (EHC). However, there are clear opportunities to make better use of this workforce. This would not only reduce pressure on GPs and be more convenient for women, but it would provide an opportunity to engage with people who are not accessing contraception in other settings."³

“Community pharmacies are one of the most frequented healthcare settings in the UK. They are often open in the evenings and weekends and are centrally located. This Inquiry heard that over 99% of people living in areas of highest deprivation are within a 20-minute walk of a community pharmacy, and as such they have an important role to play in improving health and tackling health inequalities.”³

“In recent years pharmacists have become increasingly involved in primary care, from the provision of immunisations and travel vaccinations, to the delivery of Emergency Hormonal Contraception (EHC). However, the Inquiry heard that they are significant opportunities to improve access to contraceptives in pharmacy settings; this would both be convenient for women and reduce the burden on GP and specialist providers.”³

Who can I contact if I want to know more about the commissioning and/or governance of this local project/service?

Name = XXX

Contact Details = XXX

Name = XXX

Contact Details = XXX

How does the “Implants in Pharmacy Project” link to the other NHS England Pharmacy Contraceptive Service?

The ‘Community Pharmacy Contractual Framework 5-year deal: year 4 (2022 to 2023) and year 5 (2023 to 2024)’ enables community pharmacists to provide ongoing management, via a Patient Group Direction, of routine oral contraception that was initiated in general practice or sexual health clinic. This will allow greater choice in terms of where they access their current form of contraception⁵.

Currently, NHS England are piloting a Tier 2 service enabling community pharmacists to also initiate oral contraception, via a Patient Group Direction, and provide ongoing clinical checks and annual reviews. Following a positive evaluation of the Pilot, this will be rolled out widely in October 2023.⁶

This project is different to the NHS England pilot but complimentary to it. This pilot is based on ‘The Umbrella Service’ that has been running for a number of years in Birmingham, whereby community pharmacists provide a contraception service that includes emergency, oral and injectable contraception but doesn’t currently include subdermal implants.⁷ We are implementing a pharmacy service in [input area] delivering all methods of contraception (including the subdermal implant but excluding intrauterine devices/intrauterine system methods).

References

1. NHS pharmacy contraception service tier 1 – Ongoing supply of oral contraception. Available at <https://www.england.nhs.uk/long-read/nhs-pharmacy-contraception-service-tier-1-ongoing-supply-of-oral-contraception/>. Accessed March 2023.
2. Nexplanon® summary of product characteristics 2022
3. Women’s lives, women’s rights: Full report. Available at <https://www.fsrh.org/documents/womens-lives-womens-rights-full-report/>. Accessed March 2023.
4. Letter of competence subdermal contraceptive implants techniques insertion and removal (LoC SDI-IR). Available at <https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/>. Accessed March 2023.
5. Community pharmacy contractual framework 5-year deal: year 4 (2022 to 2023) and year 5 (2023 to 2024). Available at <https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024/community-pharmacy-contractual-framework-5-year-deal-year-4-2022-to-2023-and-year-5-2023-to-2024>. Accessed March 2023.
6. NHS community pharmacy contraception service pilot. Available at <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/nhs-community-pharmacy-contraception-service-pilot#:~:text=The%20purpose%20of%20Tier%20of%20the%20pilot,not%20a%20replacement%20for%20local%20authority%20commissioned%20services>. Accessed March 2023.
7. Umbrella service. Available at <https://umbrellahealth.co.uk/our-services/pharmacy-services/>. Accessed March 2023.

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.

SIDE EFFECTS

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

Date of review of prescribing information: August 2022

© 2023 Organon group of companies. All rights reserved.

PI.NEX.22.UK.0118.IA-ORG-LDN.NORCN

JBN GB-XPL-115436
DOP March 2023

Frequencies can be defined as: Very Common ($\geq 1/10$); 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. **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
The Hewett Building, 14 Hewett Street,
London EC2A 3NP
United Kingdom

Legal Category: POM