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JBN GB-XPL-115519 DOP December 2023

Pharmacy Toolkit

Mandatory Training Pathway - Tier 1 (Ongoing monitoring and supply of repeat oral contraception prescriptions)

	Consultation skills	AND	Contraceptive counselling	AND	Emergency contraception	AND	General contraception		AND	Sexual health	
Assessment/Learning	CPPE consultation skills for pharmacy practice e-assessment		FSRH contraceptive counselling online course		CPPE emergency contraception e-learning and e-assessment		CPPE contraception e-learning and e-assessment	FSRH sexual and reproductive healthcare e-learning programme - module 3 (contraceptive choice)		CPPE sexual health in pharmacies e-learning and e-assessment	FSRH sexual and reproductive healthcare e-learning programme - module 9 (STIs)
Learning objectives	Passing this assessment will provide assurance to you, your colleagues, other HCPs and patients that you are able to recognise good practice, as well as practice that needs development. [1]		Supports HCPs to develop: • Key concepts in contraceptive counselling • Key skills for effective contraceptive counselling • Understanding good and bad consultations • Action planning to improve your contraceptive consultations [2]		To help you to identify who may need advice and support, how you can give that support and what is the best course of action. It includes information on emergency hormonal contraception, the copper-bearing and the intrauterine device. [3]		Aims to equip pharmacists with the up-to-date skills and knowledge needed to confidently support and advise patients who use or might use contraception [4]	Describes all the contraceptive methods currently available in the UK. Four sub-sections: 1. Mechanisms of action 2. Choosing contraceptive methods 3. Combined hormonal contraception (CHC) methods 4. Progestogen-only methods (oral and injectable)		Focuses on STIs Aims to support the community pharmacy team in developing and providing a sexual health service	Four sub-sections: 1. Epidemiology and transmission of STIs 2. STI testing 3. STI management 4. Partner notification when dealing with STIs
Time expectancy	45-minute time limit		2 hours		3 hours for the e-learning and 45-minute time limit for the e-assessment		6 hours for the e-learning and 45-minute time limit for the e-assessment	20-30 minutes		6 hours for the e-learning and 45-minute time limit for the e-assessment	20-30 minutes
How to access assessment/learning	1. Go to https://www.cppe.ac.uk 2. Search 'Consultation skills for pharmacy practice (2023)' and click on e-assessment 3. Login or register with CPPE to access		1. Go to https://www.fsrh.org 2. Click on 'education and training' tab 3. Click on 'FSRH Learning and Resources' from 'subject' drop down list then click search 4. Click on 'FSRH Contraceptive Counselling Free Online Course' 5. Login or register with FSRH to access		1. Go to https://www.cppe.ac.uk 2. Search 'emergency contraception' 3. Click on 'emergency contraception e-learning' or 'emergency contraception (2023) - e-assessment' 4. Login or register with CPPE to access		1. Got to https://www.cppe.ac.uk 2. Search 'contraception' 3. Click on 'contraception e-learning' or 'contraception (2023) - e-assessment' 4. Login or register with CPPE to access	1. Go to https://www.fsrh.org 2. Click on 'education and training' tab 3. Click on 'e-Learning for sexual and reproductive healthcare (eSRH)' 4. Login or register with an e-LfH account to access		1. Go to https://www.cppe.ac.uk 2. Search 'sexual health in pharmacies' 3. Click on 'sexual health in pharmacies e-learning' or 'sexual health in pharmacies (2023) -e-assessment' 4. Login or register with CPPE to access	1. Go to https://www.fsrh.org 2. Click on 'education and training' tab 3. Click on 'e-Learning for sexual and reproductive healthcare (eSRH)' 4. Login or register with an e-LfH account to access
Acronyms	• CPPE = centre for pharmacy postgraduate education • HCP = healthcare professional		• FSRH = faculty of sexual and reproductive healthcare • HCP = healthcare professional		• CPPE = centre for pharmacy postgraduate education		• CPPE = centre for pharmacy postgraduate education	• FSRH = faculty of sexual and reproductive healthcare		• CPPE = centre for pharmacy postgraduate education • STIs = sexually transmitted infections	• FSRH = faculty of sexual and reproductive healthcare • STIs = sexually transmitted infections
References	1. Consultation skills for pharmacy practice (2023). Available at https://www.cppe.ac.uk/programmes/l?t=Consult-A-07&evid=. Accessed August 2023.		2. FSRH Contraceptive Counselling Free Online Course. Available at https://www.fsrh.org/education-and-training/fsrh-contraceptive-counselling-online-course/. Accessed August 2023.		3. Emergency contraception e-learning. Available at https://www.cppe.ac.uk/programmes/l/ehc-e-03. Accessed August 2023.		4. Contraception e-learning. Available at https://www.cppe.ac.uk/programmes/l/contra-e-01/. Accessed August 2023.				

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Pharmacy Toolkit

Mandatory Training Pathway - Tier 2 (Initiation of oral contraceptives via a Patient Group Direction)

	Sexual and reproductive health	AND	Safeguarding skills	AND	Remote consultation skills	AND	Patient group directions	AND	Shared decision making	AND	Consent and history taking	AND	Documenting in patient clinical records
Assessment/Learning	FSRH sexual and reproductive healthcare e-learning programme - module 3 (contraceptive choice)	AND	FSRH sexual and reproductive healthcare e-learning programme - module 5 (contraception: compliance/side-effects)	OR	Learning for healthcare safeguarding children and young people - safeguarding children level 3	OR	Safeguarding level 3 for Community Pharmacy Teams - PQS webinar		CPPE remote consultation skills e-learning programme		Patient group directions e-learning programme		Shared decision making learning package		FSRH sexual and reproductive healthcare e-learning programme - module 2 (consent and history taking)		CPPE documenting in patient clinical records e-learning proramme
Learning objectives	Describes all the contraceptive methods currently available in the UK	AND	Addresses bleeding problems and other side effects attributable to the use of hormonal contraception. They provide step-by-step practical guidance. [5]	OR	Created for all clinical staff working with those who could potentially contribute to assessing, planning intervening and evaluating the needs of a child or young person. Topics include sudden or unexpected death in childhood, parental risk factors, unexplained injuries, disability and neglect, fabricated and induced illness and adolescents presenting with intoxication. [6]	OR	Recording of the Level 3 Safeguarding webinar tailored specifically for staff working in community pharmacies. Hosted by NHS England's Community Pharmacy and Safeguarding teams. The panel discussed the signs of abuse and what to do if these signs are recognised in community pharmacy. [7]		To support pharmacists in applying existing consultation skills when undertaking consultation via video and over the phone. [8]		To support HCPs and organisations who are considering, developing, authorising and using patient group directions to deliver healthcare services in line with legislation and NICE medicines practice guidelines. [9]		Aims to equip people with the skills and knowledge they need to have good-quality shared decision-making conversations with the people they are caring for. Made up of 6 modules: • Orientation and background • Cognitive psychology: the science of how we all make decisions • Evidence-based medicine • Probability and uncertainty • Consultation skills • Practicing shared decision making, staying up to date [10]		This course looks at medical history taking including sexual history taking and risk assessment for STIs and pregnancy. [11]		Will support pharmacy professionals with documenting in patients' clinical records to enable continuity of patient care in integrated local services. [12]
Time expectancy	20-30 minutes	AND	20-30 minutes				1 hour		2 hours and 30 minutes				4 hours		20-30 minutes		6 hours
How to access assessment/learning	1. Go to https://www.fsrh.org 2. Click on 'education and training' tab 3. Click on 'e-Learning for sexual and reproductive healthcare (eSRH)' 4. Login or register with an e-LfH account to access	AND	1. Go to https://www.fsrh.org 2. Click on 'education and training tab' 3. Click on 'e-Learning for sexual and reproductive healthcare (eSRH)' 4. Login or register with an e-LfH account to access	OR	1. Go to https://www.e-lfh.org.uk 2. Click on 'programmes' tab 3. Filter search by 'children and young people' 4. Click on 'safeguarding children and young people' 5. Login or register with an e-LfH account to access	OR	1. Go to https://portal.e-lfh.org.uk 2. Search 'Safeguarding level 3 for Community Pharmacy Teams' 3. Click on the information button 4. Login or register with e-LfH account to access		1. Go to https://www.cppe.ac.uk 2. Search 'remote consultation skills' 3. Click on 'remote consultation skills -e-learning' 4. Login or register with CPPE to access		1. Go to https://www.e-lfh.org.uk 2. Click on 'programmes' tab 3. Click on 'patient group directions' 4. Login or register with an e-LfH account to access		1. Go to https://www.nice.org.uk 2. Search 'shared decision making' 3. Click on 'shared decision making (NG197)' 4. Click on 'tools and resources' tab 5. Click on 'shared decision making learning package' 6. Click links to access modules		1. Go to https://www.fsrh.org 2. Click on 'education and training' tab 3. Click on 'e-Learning for sexual and reproductive healthcare (eSRH)' 4. Login or register with an e-LfH account to access		1. Go to https://www.fsrh.org 2. Search 'documenting in patient clinical records' 3. Click on 'documenting in patient clinical records -e-learning' 4. Login or register with CPPE to access
Acronyms	• FSRH = faculty of sexual and reproductive healthcare		• FSRH = faculty of sexual and reproductive healthcare • IUD = intrauterine device • IUS = intrauterine system				• PQS = pharmacy quality scheme		• CPPE = centre for pharmacy postgraduate education		• HCP = healthcare professional • NICE = national institute for health and care excellence				• STI = sexually transmitted infections		• CPPE = centre for pharmacy postgraduate education
References			5. Contraception: complications/side-effects. Available at https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/ Accessed August 2023.		6. Safeguarding children level 3. Available at https://www.e-lfh.org.uk/programmes/safeguarding-children/ Accessed August 2023.		7. Safeguarding level 3 for community pharmacy teams. Available at https://portal.e-lfh.org.uk/Component/Details/767185 Accessed August 2023.		8. Remote consultation skills. Available at https://www.cppe.ac.uk Accessed August 2023.		9. Patient group directions. Available at https://www.e-lfh.org.uk/programmes/patient-group-directions/ Accessed August 2023.		10. Shared decision making. Available at https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-learning-package-9142488109 Accessed August 2023.		11. Consent and history taking. Available at https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/ Accessed August 2023.		12. Documenting in patient clinical records. Available at https://www.cppe.ac.uk/programmes/l/clinical-e-02 Accessed August 2023.

Tier 3 and 4 service specification has not yet been written by the NHS

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Pharmacy Toolkit

Training Pathway - Tier 4 (Initiation of Long-Acting Reversible Contraception)

	Assessment	Registration	Cost	Time expectancy	Useful resources	Post training	Acronyms	References
Entry requirements	Successful applicants must: • Be registered with a UK or Irish medical professional regulatory body and have a licence to practice if that is required by your regulator (for regulatory bodies, please refer to the FSRH website) • Be competent in consultation skills • Have resuscitation and anaphylaxis training in line with current UK guidelines (certificate or screenshot of certificate is required) • Be competent to give intramuscular injections • Have read the current FSRH guidance on subdermal implants and be conversant with its content (https://www.fsrh.org/standards-and-guidance/fsrh-guidelines-and-statements/method-specific/) • Be able to confirm, at the time of application, that you have read the 6 principles of care and agree to abide by them in practice (outlined in https://www.fsrh.org/documents/guidance-for-those-undertaking-or-recertifying-fsrh/), it is important to have read this document prior to commencing training • Your practical training must be completed through a faculty-recognised general training programme • Purchase and pass the OTA • Complete e-SRH module 14 for LoC SDI-IR • Download LoC SDI-IR and submit your record of training[13]						• FSRH = faculty of sexual and reproductive healthcare • OTA = online theory assessment • SRH = sexual and reproductive health • LoC SDI-IR = letter of competence subdermal implants insertion and removal	13. Entry requirements. Available at https://www.fsrh.org/education-and-training/letter-of-competence-subdermal-implants-loc-sdi/. Accessed August 2023.
Online Theory Assessment	The OTA has replaced the previous EKA. A pass is required as a pre-requisite to the FSRH Letter of Competence (LoC SDI-IR)	• Register (if you don't have an FSRH website account) • Log into 'My FSRH' and scroll down to the 'FSRH Training Hub' section and click 'Browse Courses' • Then select 'OTA' [14]	£75 payable to the FSRH per attempt, paid upfront when enrolling	Sitting the OTA takes one hour and the assessment contains 50 single best answer questions[15]	https://fsrh.org/documents/online-theory-assessment-guide/ https://www.fsrh.org/education-and-training/ota/		• OTA = online theory assessment • EKA = electronic knowledge assessment • FSRH = faculty of sexual and reproductive healthcare • LoC-SDI-IR = letter of competence subdermal implants insertion and removal	14. 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/#what-how-do-i-study. Accessed August 2023.
Sexual and Reproductive Health e14 module	Comprises of 32 sessions organised around 15 different topics. Sessions are interactive and accessible.[16]	• For access you will need to register with e-Learning for Healthcare • Click 'view button' at the top right-hand corner of e-learning for healthcare (https://www.e-lfh.org.uk) to see a list of all modules[14]	Free to NHS professionals	Each module is 20-30 minutes	https://www.e-lfh.org.uk		• NHS = national health service	15. Quick guide to the online theory assessment (OTA). *Faculty of sexual and reoroductive healthcare*. November 2022.
LoC SDI-IR	Will equip the learner with evidence based knowledge, attitude and skills required to consult with a woman requesting contraception. Will enable them to provide and remove subdermal implants competently, and manage any complications or side-effects that may occur.[13]	• Log into 'My FSRH' and scroll down to the 'FSRH Training Hub' tile • Click 'Browse Courses' • Select 'Letter of Competence in Subdermal Implant Insertion & Removal (LoC SDI-IR Application)' • Click 'Go to Course'[17]	• £80 payable to FSRH for members that lasts for 5 years (no fee to recertify after the 5 years if you remain a member) • £450 payable to FSRH to non-members that lasts for 5 years (a fee will be payable to recertify after 5 years)		https://www.fsrh.org/home/	You will need to download and submit your record of training with supporting documents and signatures 1. Download a LoC SDI-IR Training Record Form 2. Complete the online evaluation of your training experience 3. Click orange button 'Submit your training record and pay fee here' to submit your documents and pay the fee 4. If you meet the criteria, your LoC will be awarded within 14 working days[14]	• FSRH = faculty of sexual and reproductive healthcare • LoC-SDI-IR = letter of competence subdermal implants insertion and removal • LOC = letter of competence	16. About the sexual and reproductive healthcare programme. Available at https://www.e-lfh.org.uk/programmes/sexual-and-reproductive-healthcare/ Accessed August 2023. 17. 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/#how-to-apply. Accessed August 2023.

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Pharmacy Toolkit

Prescribing Information

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 https://yellowcard.mhra.gov.uk 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).
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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
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
The Hewett Building, 14 Hewett Street,
London EC2A 3NP
United Kingdom
Legal Category: POM

Date of review of prescribing information: August 2022

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

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Pharmacy Toolkit

Prescribing Information

MERCILON® (Desogestrel and ethinylestradiol) Prescribing information

MERCILON®
(Desogestrel and ethinylestradiol)
PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics before prescribing

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PRESENTATION
Tablet containing 150 mcg desogestrel and 20 mcg ethinylestradiol.

USES
Oral contraception.

DOSAGE AND ADMINISTRATION
One tablet daily for 21 consecutive days, in the order directed on the pack. Each subsequent pack is started after a 7-day tablet-free interval. Refer to SPC for initiation, switching advice and management of missed tablets and gastrointestinal disturbances.

CONTRAINDICATIONS
Do not use combined hormonal contraceptives (CHCs) in the presence of any of the following conditions. If any condition appears for the first time discontinue use immediately: History of, presence of (including with anticoagulant use), known hereditary or acquired predisposition of, or risk of venous thromboembolism (VTE); Major surgery with prolonged immobilisation; Known hereditary or acquired predisposition for, presence of or risk of arterial thromboembolism (ATE) or prodromal condition; Cerebrovascular disease; Migraine with focal neurological symptoms; High risk of ATE due to one or more risk factor such as: diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia. Pancreatitis or a history thereof if associated with severe hypertriglyceridaemia; Presence or history of severe hepatic disease unless liver function values normal; Presence or history of liver tumours; Known or suspected estrogen-dependent tumours; Endometrial hyperplasia; Undiagnosed vaginal bleeding; Known or suspected pregnancy. Hypersensitivity to any of the ingredients. Concomitant use with medicinal products containing ombitasvir/ paritaprevir/ ritonavir and dasabuvir or glecaprevir/pibrentasvir.

PRECAUTIONS AND WARNINGS
Assess women prior to starting oral contraceptives, take a complete personal and family medical history, rule out pregnancy, check blood pressure and perform physical examination. This and the contraindications and warnings should guide initiation. Women's attention should be drawn to the risk and symptoms of VTE and ATE and what to do in the event of suspected symptoms. **Circulatory disorders**: VTE: The use of any HC increases the risk of VTE compared with no use. An increased risk of VTE associated with the use of oral contraceptives is well established. Mercilon may have up to twice the level of risk compared with products that contain levonorgestrel, norgestimate or norethisterone which are associated with the lowest risk of VTE. The decision to use any product other than one with the lowest VTE risk must be discussed with the women. Whether women take CHCs or not, the number of VTEs per year is fewer than the number expected during pregnancy or in the postpartum period. VTE is fatal in 1-2% of cases. Risk of VTE during the postpartum period should be considered when restarting. ATE: Epidemiological studies have associated the use of CHCs with an increased risk for ATE or for cerebrovascular accident. Do not prescribe a CHC if the benefit and risks is considered negative. In the event of VTE/ATE symptoms urgent medical attention should be sought and healthcare professional informed of CHC use. An increase in frequency or severity of migraine during CHC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of CHCs. Refer to SPC for risk factors and signs and symptoms of thrombotic events. **Tumours**: Increased risk of cervical cancer in long term users of COCs reported in some studies, but may be due to effects of sexual behaviour and other factors such as human papilloma virus. Epidemiological studies report there is a slightly increased relative risk of having breast cancer diagnosed in women currently using COCs. In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of COCs. **Other conditions**: Women with hypertriglyceridemia, or a family history may be at an increased risk of pancreatitis when using CHCs. Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. If sustained clinically significant hypertension develops during the use, then CHC should be withdrawn and hypertension treated. CHC use can be resumed once normotensive values can be achieved with antihypertensives. Jaundice and/or pruritus related to cholestasis, gallstone formation, porphyria, SLE, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis and otosclerosis-related hearing loss have been reported to occur/deteriorate with pregnancy and CHC use. Acute or chronic disturbances of liver function may necessitate discontinuation of CHC use until markers return to normal. Diabetic women should be carefully observed while taking CHCs. Crohn's disease and ulcerative colitis have been associated with CHC use. Chloasma may occasionally occur. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking this preparation. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not use. Missed tablets, concomitant medications or gastrointestinal disturbances may reduce efficacy. Depressed mood and depression can be associated with hormonal contraceptive use. Depression is a risk factor for suicidal behaviour and suicide. Advise women to contact their physician if they develop mood changes and depressive symptoms.

INTERACTIONS:
Interactions between oral contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Interactions can occur with medicinal or herbal products that induce microsomal enzymes, specifically cytochrome P450 enzymes (CYP) (e.g. phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, rifambutin and possibly also oxcarbazepine, modafinil, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir), non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz) and products containing St. John's wort). Co-administration of CHCs with combinations of HIV protease inhibitors (e.g., nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine), and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g., boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins, including etonogestrel. Concomitant use of strong or moderate CYP3A4 inhibitors may increase serum concentrations. Refer to SPC for advice on additional contraceptive requirements. The prescribing information of concomitant medications should be consulted to identify potential interactions.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side-effects.

Serious side effects: hypersensitivity, venous and arterial thromboembolic events, breast and cervical cancer and liver tumours.
Common (>1/100): depressed or altered mood, headache, nausea, abdominal pain, breast tenderness, breast pain, weight increase.

BASIC NHS COST
3 blisters x 21 tablets: £8.44

MARKETING AUTHORISATION HOLDER
Organon Pharma (UK) Limited, The Hewett Building, 14 Hewett Street, London EC2A 3NP, United Kingdom

MARKETING AUTHORISATION NUMBER
PL 00025/0598

LEGAL CATEGORY POM

Date of review of Prescribing Information: September 2023

PI.MRC.22.UK.0151.IA-ORG-LDN.NORCN

For UK Healthcare Professionals and ORDMs only.

Prescribing Information can be found at the end of this document (on pages 4, 5, 6 and 7).

This document is developed by collaboration with UK sexual health commissioners.
All training and assessments are written and provided by either the FSRH or CPPE and accessed through e-learning, not Organon.
This document was developed and all courses accessed August 2023
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JBN GB-XPL-115519 DOP December 2023

Pharmacy Toolkit

Prescribing Information

MARVELON® (Desogestrel and ethinylestradiol) Prescribing information

MARVELON®
(Desogestrel and ethinylestradiol)
PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics 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 Organon website and be taken to the MHRA website.

PRESENTATION
Tablet containing 150 mcg desogestrel and 30 mcg ethinylestradiol.

USES
Oral contraception.

DOSAGE AND ADMINISTRATION:
One tablet daily for 21 consecutive days, in the order directed on the pack. Each subsequent pack is started after a 7-day tablet-free interval. Refer to SPC for initiation, switching advice and management of missed tablets and gastrointestinal disturbances.

CONTRAINDICATIONS
Do not use combined hormonal contraceptives (CHCs) in the presence of any of the following conditions. If any condition appears for the first time discontinue use immediately: History of, presence of (including with anticoagulant use), known hereditary or acquired predisposition of, or risk of venous thromboembolism (VTE); Major surgery with prolonged immobilisation; Known hereditary or acquired predisposition for, presence of or risk of arterial thromboembolism (ATE) or prodromal condition; Cerebrovascular disease; Migraine with focal neurological symptoms; High risk of ATE due to one or more risk factor such as: Diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia. Pancreatitis or a history thereof if associated with severe hypertriglyceridaemia; Presence or history of severe hepatic disease unless liver function values normal; Presence or history of liver tumours; Known or suspected estrogen-dependent tumours; Endometrial hyperplasia; Undiagnosed vaginal bleeding; Known or suspected pregnancy. Hypersensitivity to any of the ingredients. Concomitant use with medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir.

PRECAUTIONS AND WARNINGS
Assess women prior to starting oral contraceptives, take a complete personal and family medical history, rule out pregnancy, check blood pressure and perform physical examination. This and the contraindications and warnings should guide initiation. Women's attention should be drawn to the risk and symptoms of VTE and ATE and what to do in the event of suspected symptoms.
Circulatory disorders: VTE: The use of any HC increases the risk of VTE compared with no use. An increased risk of VTE associated with the use of oral contraceptives is well established. Marvelon may have up to twice the level of risk compared with products that contain levonorgestrel, norgestimate or norethisterone which are associated with the lowest risk of VTE. The decision to use any product other than one with the lowest VTE risk must be discussed with the women. Whether women take CHCs or not, the number of VTEs per year is fewer than the number expected during pregnancy or in the postpartum period. VTE is fatal in 1-2% of cases. Risk of VTE during the postpartum period should be considered when restarting. ATE: Epidemiological studies have associated the use of CHCs with an increased risk for ATE or for cerebrovascular accident. Do not prescribe a CHC if the benefit and risks is considered negative. In the event of VTE/ATE symptoms urgent medical attention should be sought and healthcare professional informed of CHC use. An increase in frequency or severity of migraine during CHC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of CHCs. Refer to SPC for risk factors and signs and symptoms of thrombotic events. **Tumours**: Increased risk of cervical cancer in long term users of COCs reported in some studies, but may be due to effects of sexual behaviour and other factors such as human papilloma virus. Epidemiological studies report there is a slightly increased relative risk of having breast cancer diagnosed in women currently using COCs. In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of COCs. **Other conditions**: Women with hypertriglyceridemia, or a family history may be at an increased risk of pancreatitis when using CHCs. Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. If sustained clinically significant hypertension develops during the use, then CHC should be withdrawn and hypertension treated. CHC use can be resumed once normotensive values can be achieved with antihypertensives. Jaundice and/or pruritus related to cholestasis, gallstone formation, porphyria, SLE, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis and otosclerosis-related hearing loss have been reported to occur/deteriorate with pregnancy and CHC use. Acute or chronic disturbances of liver function may necessitate discontinuation of CHC use until markers return to normal. Diabetic women should be carefully observed while taking CHCs. Crohn's disease and ulcerative colitis have been associated with CHC use. Chloasma may occasionally occur. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking this preparation. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not use. Missed tablets, concomitant medications or gastrointestinal disturbances may reduce efficacy.
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.

INTERACTIONS
Interactions between oral contraceptives and other drugs may lead to breakthrough bleeding and/or contraceptive failure. Interactions can occur with medicinal or herbal products that induce microsomal enzymes, specifically cytochrome P450 enzymes (CYP) (e.g. phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, rifambutin and possibly also oxcarbazepine, modafinil, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir), non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz) and products containing St. John's wort) . Co-administration of CHCs with combinations of HIV protease inhibitors (e.g., nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g., nevirapine), and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g., boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins, including etonogestrel. Concomitant use of strong or moderate CYP3A4 inhibitors may increase serum concentrations. Refer to SPC for advice on additional contraceptive requirements. The prescribing information of concomitant medications should be consulted to identify potential interactions.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side-effects.

Serious side effects: hypersensitivity, venous and arterial thromboembolic events, breast and cervical cancer and liver tumours.
Common (>1/100): depressed or altered mood, headache, nausea, abdominal pain, breast tenderness, breast pain, weight increase.

BASIC NHS COST:
3 blisters x 21 tablets: £7.10

MARKETING AUTHORISATION HOLDER
Organon Pharma (UK) Limited, The Hewett Building, 14 Hewett Street, London EC2A 3NP, United Kingdom

MARKETING AUTHORISATION NUMBER
PL 00025/0596

LEGAL CATEGORY POM

Date of review September 2023

PI.MRV.22.UK.0148.IA-ORG-LDN.NORCN

For UK Healthcare Professionals and ORDMs only.

Prescribing Information can be found at the end of this document (on pages 4, 5, 6 and 7).

This document is developed by collaboration with UK sexual health commissioners.
All training and assessments are written and provided by either the FSRH or CPPE and accessed through e-learning, not Organon.
This document was developed and all courses accessed August 2023
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JBN GB-XPL-115519 DOP December 2023

Pharmacy Toolkit

Prescribing Information

CERAZETTE® (Desogestrel) Prescribing information

CERAZETTE®
(Desogestrel)
PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics 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 Organon website and be taken to the MHRA website.

PRESENTATION
Three sachets of strips of 28 tablets, each containing 75 micrograms desogestrel.

USES
Contraception.

DOSAGE AND ADMINISTRATION
One tablet daily, at about the same time. No pill-free week between strips. When no preceding hormonal contraceptive use (in the past month) initiate therapy on day 1 of the woman's natural cycle (first day of menstrual bleeding). Starting on days 2-5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of therapy. Refer to SmPC for full advice on starting Cerazette; missed tablets; changing from other combined oral contraceptives (COCs) and post-partum.
Special populations:
Hepatic impairment: contra-indicated. Renal impairment: No data Paediatric population: No data in patients under 18 years.

CONTRA-INDICATIONS
Active venous thromboembolic disorder, presence or history of severe hepatic disease with current abnormal liver function tests, known or suspected sex-steroid sensitive malignancies, undiagnosed vaginal bleeding, hypersensitivity to any ingredients.

PRECAUTIONS
Women currently using COCs have a slightly increased risk of having breast cancer diagnosed. The risk in users of progestogen only pills is possibly of similar magnitude to that associated with COCs. This risk is low compared to the risk of getting breast cancer ever in life. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both.
A biological effect of progestogens on liver cancer cannot be excluded. Refer to a specialist if acute or chronic disturbances of liver function occur. Benefit/risk assessment should be made in women with liver cancer.
Epidemiological studies have associated the use of COCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). It is unclear whether desogestrel used alone carries the same risk. Discontinue in the event of a thrombosis. Consider stopping prior to long term immobilisation due to surgery or illness. Caution patients with a history of thromboembolic disorders. Consider discontinuation if hypertension develops. Monitor patients with diabetes during the first months of use. Effects on bone density are unknown. Ectopic pregnancy should be considered in woman with amenorrhoea or abdominal pain. Chloasma may occasionally occur. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Cerazette. COCs may affect certain laboratory tests. Whether this applies to POP is unknown. Efficacy may be reduced in the event of missed tablets, gastro-intestinal disturbances, or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel. Depressed mood and depression can be associated with hormonal contraceptive use. Depression is a risk factor for suicidal behaviour and suicide. Advise women to contact their physician if they develop mood changes and depressive symptoms.

Drug Interactions: Refer to SmPCs of concomitant medications to identify potential interactions. Microsomal enzyme inducers can increase clearance of sex hormones and may lead to breakthrough bleeding and/or contraceptive failure. Reduced efficacy may be seen with the microsomal enzyme inducers barbiturates, bosentan, carbamazepine, phenytoin, primidone, rifampicin, efiravenz, and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate, rifabutin and products containing St John's Wort. Enzyme induction can occur after a few days of treatment, peaking within a few weeks and may last up to 4 weeks after discontinuation. Advise short-term users of enzyme inducers on additonal barrier contraception. Cerazette is not recommended for patients on long-term therapy with enzyme inducers. Co-administration of contraceptive hormones with some HIV/HCV medications can increase or decrease plasma concentrations of progestins which may be clinically relevant in some cases. Concomitant use of strong or moderate CYP3A4 inhibitors may increase serum concentration of progestins, including etonogestrel, the active metabolite of desogestrel. Hormonal contraceptives may interfere with metabolism of other drugs, and therefore increase or decrease their plasma or tissue concentrations.

Pregnancy and Lactation: Not indicated during pregnancy. Cerazette did not appear to influence breast milk production or quality in clinical trials. However, there have been infrequent postmarketing reports of a decrease in breast milk production. Small amounts of the metabolite etonogestrel are excreted with the milk. Limited long-term follow-up data (up to 2.5 yrs) on children who were breast-fed do not indicate any differences compared to those whose mother used a copper IUD. However, development and growth of the nursing infant should be carefully observed. Please refer to SmPC for information on return to fertility.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side-effects.
Common (≥1/100): irregular bleeding, amenorrhoea, headache, weight gain, breast pain, nausea, acne, mood changes, depressed mood, decreased libido.
Serious (not known): hypersensitivity reactions, including angioedema and anaphylaxis
Other less common and rarely reported side effects are listed in the SmPC.

PACKAGE QUANTITIES AND BASIC NHS COST:
3 x 28 tablets £9.55

Marketing Authorisation Number:
PL 00025/0562

Marketing Authorisation Holder:
Organon Pharma (UK) Limited,
The Hewett Building, 14 Hewett Street,
London EC2A 3NP, United Kingdom

Legal Category: POM

Date of review of prescribing Information: August 2022

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