South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF THE COMBINED TRANSDERMAL PATCH (EVRA®)

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:			
Position of Signatory	**Name**	**Signed**	**Date**
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply Evra® to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from: 1st October 2017
Review date: Aug 2019. Expires on 31st Oct 2019
Replaces PGD3416

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply Evra® as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Hold a recognised qualification in contraception/sexual health (ENB 901, 8103, or equivalent post-registration qualification; an introduction to contraception is not sufficient)
3. Is competent in the assessment of individuals using Fraser guideline
4. Has undergone regular training and updating in safeguarding children and vulnerable adults
5. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
6. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
7. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
8. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
9. All registered nurses details and signature must be entered onto the PGD
10. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Norelgestromin 203 micrograms/24 hours /ethinylestradiol 33.9 micrograms /24 hours approx transdermal contraceptive system (Evra®)
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Transdermal Patch
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Contraception
Inclusion Criteria	Any individual (age from 13 to 50 years of age) presenting for contraception and who has no contraindications.
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Under 16 years of age and assessed as not competent using Fraser guidelines • Known hypersensitivity to any constituent of the combined transdermal patch • Less than 21 days post-partum • Breast feeding and less than 6 months post-partum • Individual weighing 90kg or above **Cardiovascular Disease** • Age 35 or more and a smoker, or stopped smoking less than one year ago • BMI equal to or greater than 35kg/m^2 • BP greater than140/90mmHg or controlled hypertension • Two or more risk factors for cardiovascular disease such as over 35 years of age, smoking, diabetes, hypertension, obesity (BMI 30-35 kg/m^2) • Hyperlipidaemia • Current or past history of ischaemic heart disease, stroke or transient ischaemic attack, MI • Current or past history of venous

	thromboembolism (including risk of) • First degree relative with venous thromboembolism under 45 years of age • Known thrombogenic mutations e.g. Factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies • Complicated valvular or congenital heart disease e.g. with pulmonary hypertension, atrial fibrillation or history of subacute bacterial endocarditis • Diabetes with end organ disease • Significant or prolonged immobility including planned major surgery **Neurological Conditions** • Current or past history of migraine with neurological symptoms including aura at any age • Migraine without aura, first attack when on oestrogenic method of contraception **Cancers** • Current or past history of breast cancer • Undiagnosed breast mass (for initiation of method only) • Carrier of known gene mutations associated with breast cancer e.g. BRCA1 • Benign liver tumour, hepatic adenomes or carcinomas • Malignant liver tumour (hepatoma) • Carcinoma of the endometrium **Gastro-intestinal Conditions** • Viral hepatitis, acute or flare • Severe decompensated cirrhosis • Gall bladder disease; symptomatic, medically treated • Gall bladder disease; current, symptomatic • Cholestasis (past combined hormonal contraception (CHC) related) • Abnormal liver function relating to acute or chronic hepatic disease **Other Conditions** • Interacting medicines –see current BNF on interactions (This includes the use of potent enzyme inducers in the past 4 weeks) • Raynaud's disease; secondary, with lupus anticoagulant • Systemic Lupus Erythematosus (SLE) with positive or unknown anti-phospholipid antibodies • Undiagnosed abnormal vaginal bleeding • Local issues e.g. skin disorders

	Individual wishes to see a doctor <u>Cautions:</u> • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure/uncertain • Migraine developing or worsening whilst using the patch
Action if excluded or patient declines	• Refer to appropriate doctor/Independent nurse prescriber • Discuss/offer alternative contraceptive method • Document all actions taken • Record the refusal in the clinical record • Refer to appropriate doctor/independent nurse prescriber where required
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Transdermal
Dose	• One patch - The CTP releases 33.9 mcg EE and 203 mcg Norelgestromin per 24 hours over a 7 day period
Administration Schedule	• A single patch applied at the same time each week once weekly for 3 weeks, followed by a seven (7) day patch free interval, starting on day 1-5 of the menstrual cycle with no need for additional protection • The patch can be started as quick start at any time after day 5 if it is reasonably certain that the individual is not pregnant. Additional contraception is then required for 7 days after starting. Starting the CTP as quick start after levonorgestrel emergency contraception, additional contraception is required for 7 days. CTP can only be used from day 5 after ulipristal. Quick start cannot be used after Ulipristal emergency contraception For guidance on changing from one contraceptive

	method to another, and when to start after an abortion and post partum, refer to Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines. <u>Quantity to Supply:</u> Initial supply nine (9) patches for three months Subsequent supply up to thirty six (36) patches for twelve months (by local agreement) <u>Duration of Treatment:</u> For as long as the individual requires the patch and for as long as the individual has no contraindications to use of the patch. Minimum 3 months supply, maximum 12 months.
Warnings/Adverse Reactions	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information. The patch is well tolerated. Some of the common side effects are; • Nausea • Breast tenderness • Headache • Temporary disturbances of bleeding patterns • Changes in mood • Fluid retention • Skin irritation **Serious Symptoms** • The individual should stop using the patch and see a doctor urgently if she experiences calf swelling, heat or pain in calf, shortness of breath, chest pain or haemoptysis • The individual should seek advice if she experiences her first ever migraine or increased frequency or severity of existing migraines In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate independent practitioner • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious

	adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss how to apply • Explain mode of action, side effects, benefits and how to use the medication • Advise about the risks of the medication including failure rates and serious side effects and the actions to be taken • Advise on what to do if the individual forgets to change the patch or if the patch detaches. • Provide a copy of the FPA leaflet on the patch • Offer condoms and advise on safer sex practices. • Advice on storage and disposal of the patch according to manufacturer's instructions • Ensure individual knows what to do if her medical condition changes in the future • Ensure she has the contact details of the service Follow Up: • Individual to return to clinic if she has any concerns • Review in three (3) months after initial supply, then annually as appropriate or by local agreement.
Use in pregnancy and lactation	**Pregnancy:** Not appropriate for PGD **Lactation:** Appropriate for PGD
Records	The nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details if registered • Attendance date • Reason for attendance • Past and present medical and family history, including drug history and history of cervical cytology • Any known allergy • Initial examination to include body mass index (BMI) and blood pressure recording and thereafter according to local policy • Any advice given about the medication including side effects, benefits, how to dispose of the

	patch after removal and when and what to do if any concerns • Details of any adverse drug reactions and any action taken • Any referral arrangements • Any supply outside the terms of the product licence • The consent of the individual • If individual is under 16 years of age, document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Record the name of the medication, number of patches supplied e.g. Evra ® x 9 with batch numbers and expiry dates according to local policy and PGD number recorded. • Record any follow up arrangements • Signature and designation of the nurse who supplied the medication (follow local procedures for computer records)