NHS Salford Clinical Commissioning Group

Salford City Council

PATIENT GROUP DIRECTION FOR THE SUPPLY OF

ULIPRISTAL 30MG TABLET

By registered Pharmacists for Emergency Contraception in Community Pharmacy

Version 2.1

Valid from: 01/02/2020

Expires on: 31/01/2022

Updates since Version 2.0

- None

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD) FOR

ULIPRISTAL 30MG TABLET	P.O.M. [Prescription Only Medicine]

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Salford City Council
Address:	Public Health Department, Salford Civic Centre, Unity House, Chorley Road, Salford, M27 5AW
Telephone:	0161 793 3585

Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr Peter Budden	GP Prescribing Lead, Salford CCG	01/02/2020	2.1
Claire Vaughan	Head of Medicines Optimisation, Salford CCG	01/02/2020	2.1
Dr Muna Abdel Aziz	Director of Public Health, Salford City Council	01/02/2020	2.1

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION

Updates

REVISION DATE	SUMMARY OF CHANGES	ACTION BY	VERSION
March 2017		Alicia Robson	1.0
December 2017	▪ Updated in line with new FSRH guidance published March 2017 ▪ New recommendations - all products containing progestogen or progesterone are avoided for 5 days after ulipristal has been taken to avoid compromising the ability of ulipristal to delay ovulation.	Alicia Robson	2.0
October 2019	▪ None	Alicia Robson	2.1

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PGD Development

Originally developed / Reviewed by:	Alicia Robson (Author)	Medicines Optimisation Pharmacist, Salford CCG
	Dr Peter Budden	GP Prescribing Lead, Salford CCG
	Claire Vaughan	Head of Medicines Optimisation, Salford CCG

Date applicable:	1st February 2020
Review date:	1st December 2021
Expiry date:	31st January 2022

PGD Authorisation

This Patient Group Direction has been approved for use in the Salford City Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Head of medicines optimisation, Salford CCG)	**Claire Vaughan**		4/2/2020
Doctor (GP Prescribing Lead Salford CCG)	**Dr Peter Budden**		4/2/20
Salford City Council (Director of Public Health)	**Dr Muna Abdel Aziz**		**31/01/2020**

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1. Characteristics of Staff

Qualifications required	▪ Pharmacist with current General Pharmaceutical Council registration. ▪ Work in a community pharmacy within Salford City Council area.
Additional requirements	▪ Has undertaken training in the use of PGDs. ▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies appropriate to this PGD, as detailed in the Centre for Postgraduate Pharmacy Education (CPPE) and NHS Health Education England *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document (http://www.cppe.ac.uk/sp/sp4.asp?PID=189&ID=203). ▪ Is competent in the assessment of the individuals using Fraser Guidelines.
Continued training requirements	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception. ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document. ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education England *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document.

The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of the training received.

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2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies	• Sexual health services provided by community pharmacies commissioned by Salford City Council. • A patient requesting oral emergency contraception who presents between 72 – 120 hours of unprotected sexual intercourse (UPSI) or potential contraception failure.
Criteria for inclusion	Women with spontaneous menstrual cycles presenting within 72 to 120 hours of UPSI or potential contraception failure (e.g. condom failure; severe vomiting/diarrhoea whilst on oral hormonal contraception) and who: • Have no known contraindications to progestogen in their known medical history. • Understands the risks, benefits and side effects. • Meet Fraser Guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.* • Are competent to consent to treatment. • Have been offered the option of an intrauterine device. If referring for a post-coital intrauterine device, oral emergency hormonal contraception should be administered if within PGD and acceptable to the patient. • Has reached the menarche Patient has received ulipristal acetate emergency contraception but has vomited within **three** hours of taking it (provided they are still within 120 hours of UPSI).
Criteria for exclusion	▪ UPSI up to 72 hours ago – Advise woman that levonorgestrel is available - refer to levonorgestrel PGD. ▪ UPSI more than 120 hours ago. ▪ Allergy/known intolerance to progestogen or other product ingredients. ▪ Confirmed pregnancy. (Suspected pregnancy should be excluded using a pregnancy test.) ▪ Women less than 21 days post-partum. ▪ Women less than 5 days following termination of pregnancy or miscarriage, ▪ Undiagnosed vaginal bleeding. ▪ Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. ▪ Third party requests. ▪ Current contraception method used correctly.

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Criteria for exclusion continued	▪ Acute porphyrias. ▪ Severe asthma treated by oral glucocorticoids. ▪ Currently taking (or stopped taking up to four weeks ago) hepatic enzyme inducing medication including: o Primidone, phenobarbital, phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, rifabutin, ritonavir (long term), griseofulvin, efavirenz and nevirapine. *(See BNF and ellaOne SPC https://www.medicines.org.uk/emc/medicine/22280/SPC/ellaOne+30+mg/#PRODUCTINFO for full details)*
Cautions (including any relevant action to be taken)	▪ Effectiveness of ulipristal could be reduced if a progestogen has been taken prior to taking ulipristal. ▪ All products containing progestogen or progesterone should be avoided for 5 days after ulipristal has been taken to avoid compromising the ability of ulipristal to delay ovulation. Barrier methods should be used until next menstrual period. ▪ Severe intestinal malabsorption syndromes e.g. Crohn's disease, might impair the efficacy of ulipristal. Advise patient accordingly. ▪ Efficacy and absorption of ulipristal may be reduced with concomitant use of proton pump inhibitors, H_2 receptor antagonists and other drugs that increase gastric pH. Advise patient accordingly. ▪ Severe hepatic impairment. ▪ Breast feeding is not recommended for 7 days after taking ulipristal. ***The Cu-IUD can offer a more effective option and it is important that patients understand the risk of emergency contraception failure.***
Action if excluded	▪ Refer to appropriate doctor or sexual health clinic. ▪ Document all actions taken.
Action if patient or carer declines treatment	▪ Make individual aware of the risks of not receiving treatment. ▪ Refer to doctor or sexual health clinic. ▪ Document all actions taken.

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3. Details of medicine

Name, strength & formulation of drug	Ulipristal acetate (ellaOne®) 30mg tablet
Presentation	Treatment should be supplied in a suitably labelled box.
Storage	Store below 25°C. Store in the original packaging to protect from moisture. Keep the blister in the outer carton to protect from light.
Legal category	POM
Black Triangle ▼	No
Unlicensed / off label use	Not applicable.
Route / method	Oral
Dose and frequency	One 30mg tablet to be taken as a single dose between 72 and 120 hours after UPSI. *If patient experiences vomiting within three hours of taking ulipristal, a second supply is allowed providing it is taken within 120 hours of UPSI.*
Quantity to be administered and/or supplied	Single dose of ulipristal acetate 30mg tablet. It is good practice to observe the patient consuming the medication unless they are breast feeding, when they can be allowed to take it away for later consumption if necessary. This must occur within the 120 hour window.
Maximum or minimum treatment periods	Single episode of treatment – treatment may be repeated in the same cycle if appropriate. See Dose and Frequency section.
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.
Drug interactions	▪ If the patient is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this PGD is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the SPC (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) ▪ In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. ▪ If the requirements of this PGD cannot be complied with, the patient must be referred to a suitable independent prescriber.)

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Identification & management of adverse reactions

Very common and common adverse effects	
Abdominal pain	Back pain
Diarrhoea	Dizziness
Fatigue	Gastro-intestinal disturbances
Headache	Menstrual irregularities
Muscle spasms	Nausea
Vomiting	

For a full adverse effects profile, refer to the SPC (www.medicines.org.uk) or the most current edition of the BNF (www.bnf.org)

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk)

4. Records

Records	The pharmacist must keep a record of the consultation as required in the service specification for a period of time in line with records management: NHS code of practice (https://digital.nhs.uk/information-governance) and service specification. The minimum required information to be collected is: ▪ Informed consent has been given ▪ Patient's name, postcode, date of birth. ▪ Dose supplied. ▪ Date administered/issued – if not, detail why. ▪ Advice given. ▪ Supply documented on Patient Medical Record. ▪ Adverse drug reactions documented. ▪ Name, signature and GPhC number of pharmacist who supplied the medication. ▪ Expiry date ▪ Batch number ▪ If under 16 years 'Fraser Competence Checklist' completed Records management: NHS Code of Practice recommends the following storage periods for Sexual Health paper records: ▪ **8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death**. Computerised patients medication records can be used where considered appropriate. Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

5. Patient Information

Written information to be given to the patient or carer	The patient should be given the following written information if appropriate: ▪ The product specific patient information sheet supplied with the medicine. ▪ Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at http://www.fpa.org.uk/resources/downloads) to patients
Advice to be given to the patient or carer	The patient should be given the following information verbally if appropriate and requested: ▪ Effectiveness of method, dependent on length of time from UPSI/ potential contraceptive failure to treatment. ▪ Beneficial effects, side effects and risks should be discussed. ▪ Effectiveness of Ulipristal could be reduced if a progestogen has been taken prior to taking Ulipristal. ▪ The FSRH recommends that all products containing progestogen or progesterone should be avoided for **5 days** after ulipristal has been taken to avoid compromising the ability of Ulipristal to delay ovulation. Barrier methods should be used until next menstrual period. ▪ How to take the pill correctly, preferably as an immediate dose in the pharmacy. Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. ▪ Manufacturer advises that breast feeding should be avoided for 7 days after taking ulipristal. ▪ If vomiting occurs within three hours of taking, a repeat dose is required. ▪ When to seek medical advice. ▪ To refer to Sexual Health Clinic or GP if no/ light period up to 3 weeks after treatment. ▪ Discuss on-going contraception including Quick Starting Contraception guidance (recommending starting contraception >5 days after Ulipristal emergency contraception has been taken, with additional protection as appropriate for the method used). ▪ Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG30 October 2005. ▪ Supply and/or encourage use of condoms and reinforce the safer sex message. ▪ Recommend sexually transmitted infections screening. Pharmacies which provide chlamydia screening should offer testing kits to 15-24 year olds. ▪
Labelling	Medication supplied to the patient must be labelled in accordance with current legislation.

6. References used to develop this PGD

1. Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit:
   - Emergency Contraception. Clinical Guidance, March 2017 (updated December 2017) Accessed on 15h December 2019
   - Contraceptive Choices for Young People. Clinical Guidance. March 2010, amended May 2019. Accessed 15th December 2019

2. Manufacturers' Summaries of Product Characteristics (SPC)
   - ellaOne® 30mg tablet HRA Pharma Uk and Ireland Ltd. Date of last revision of the text 19h November 2018. Accessed 15th December 2019.

3. General Pharmaceutical Council
   - Standards for pharmacy professionals. May 2017. Accessed 15th December 2019

4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for community pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction. Accessed 15th December 2019

PATIENT GROUP DIRECTION (PGD) FOR

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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content;
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and ongoing training requirements to continue to use the PGD safely

Named Healthcare Professional: _____

Designation: _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer: _____
/ Contractor

Address of Employer: _____
/ Contractor

_____

_____

_____

Signature of Employer: _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional: _____

Date: _____

One copy to be retained by the named healthcare professional

One copy to be retained by the employer / contractor

The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.