Patient Group Direction For The Administration / Supply Of levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception By Registered Nurses, Emergency Care Practitioners And Named Community Pharmacists

Developed By Devon Patient Group Direction Review Group

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
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<tbody>
<tr>
<td>Physician</td>
<td>Dr Ben Leger</td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Joy Davey</td>
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</table>

Review Date: May 2010

Local Organisation Authorisation

Authorised by…………………………………………………………………………

On behalf of…………………………………………………………………………

Signed………………………………………………………………………………

Date of Implementation…………………………………………………………

Practice Authorisation

Authorised by (Name & Address of practice)

………………………………………………………………………………

………………………………………………………………………………

………………………………………………………………………………

Signed (Senior GP for practice nurses)

………………………………………………………………………………

Date:……………………………………………………………………..
Patient Group Direction For The Administration/Supply Of levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception By Registered Nurses, Emergency Care Practitioners And Named Community Pharmacists

1. Clinical Condition

Definition of condition/situation
- Emergency hormonal post-coital contraception in females with a history of unprotected sexual intercourse/failed contraception
- Repeat dose of emergency hormonal post coital contraception in females who have vomited within three hours of receiving emergency hormonal post-coital contraception

Criteria for inclusion

Registered Nurses and Emergency Care Practitioners (ECPs)
- Females aged 13 years and above, presenting within 72 hours of unprotected sexual intercourse or failed contraception whose need for emergency contraception is defined by the protocol.
- A patient has received EHC but has vomited within 3 hours of the dose (providing the repeat dose will be taken within 72 hours of unprotected sexual activity).

Pharmacists
- Females aged 13 – 19 years of age, presenting within 72 hours of unprotected sexual intercourse or failed contraception whose need for emergency contraception is defined by the protocol.
- A patient aged 13 – 19 years of age who has received EHC from the named pharmacist but has vomited within 3 hours of the dose (providing the repeat dose will be taken within 72 hours of unprotected sexual activity).

Criteria for exclusion

Pharmacists only
- Female 20 years of age and over

Registered Nurses, Emergency Care Practitioners (ECPs) and Pharmacists

Female:
- Under 13 years of age
- Under 16 years of age who is not considered to be ‘Fraser competent’
- Over 16 years of age but who is considered to be a vulnerable adult

Immediate referral of female to GP, Contraceptive Services or Out of Hours services for EHC.
Child protection issues must be addressed as per training.
- Presenting more than 72 hours after any unprotected sexual activity
- With established or suspected pregnancy
- Hypersensitive to any of the constituents of Levonelle® 1500
- Taking ciclosporin – increased risk of toxicity of ciclosporin
- Active acute porphyria
- With severe liver disease
- Any situation where the pharmacist has reservations about supplying
- Representatives of females requiring emergency hormonal contraception - supply to a 3rd party is not permitted
- Delivered of baby in last 3 weeks EHC is not required in these circumstances

Caution

- If patient is taking any other medications consult BNF Appendix 1 and protocol for any potential interactions.
- In females aged 13-16 years consider child protection issues as per training
- Taking Liver Enzyme Inducing Drugs - such as barbiturates (including primidone and phenobarbital/phenobarbitone), carbamazepine (Tegretol®), phenytoin (Epanutin®), oxcarbazepine, topiramate, rifampin, rifabutin, griseofulvin, Ritonavir and other drugs to treat HIV – check individual drugs, herbal preparations containing Hypericum perforatum (St John’s Wort), bosentan, oral tacrolimus, modafinil, proton pump inhibitors – check individual drugs (see dose adjustments below).
Caution (continued)

- Anticoagulants – the anticoagulant effect of warfarin and phenindione is enhanced: the patient’s GP should be informed to ensure follow up occurs and INR is checked 3 days later.
- Taking the contraceptive pill (see protocol)
- Breastfeeding – EHC not thought to be harmful but potential exposure can be reduced if the woman takes the tablets immediately after feeding
- Patient identified as having the following significant health problems: Severe hypertension, Diabetes Mellitus and associated vascular or neuropathic complications, ischaemic heart disease, stroke or a past history of breast cancer – obtain further specialist advice if unsure
- Suffering from severe malabsorption syndromes, such as Crohn’s Disease – obtain specialist advice (see protocol)

Action if excluded

- Immediate referral to GP, Contraception Services or Out of Hours services for further assessment and treatment.
- N.B. Intervention with EHC at 72-120 hours after UPSI is unlicensed and less effective than an IUD, but better than non-intervention and the patient should be referred urgently to GP, Out of Hours services or Contraceptive Services.

Action if patient refuses medication

- Refer to GP, Contraception Services or Out of Hours services and advise to obtain a pregnancy test
- Document in patient record where applicable

2. Characteristics of Staff

Qualifications required

The practitioner must hold one of the following registrations:

- Registered Nurse or Midwife
- Registered Pharmacist, commissioned by the Trust to provide Emergency Contraceptive Services as a Locally Enhanced Service.
- Emergency Care Practitioner (ECP) with an appropriate registration to allow them to operate under a PGD.

Additional requirements

Updating with relevant evidence of continued professional development and maintenance of competencies.

Registered Nurses and Emergency Care Practitioners (ECPs)

- Attendance at foundation level child protection training as agreed with Trust named nurse and lead for child protection through Trust child protection training programme.
- Attendance at annual updates for child protection
- Successful completion of and assessed as competent to supply EHC though one of the following:
  - Trust approved training programme, provided by Contraceptive Services [Present curriculum includes – the EHC PGD, contraception, ‘Fraser competency’, referrals and communication skills]
  - Family Planning Training.
  - Advanced care in clinical practice in obstetrics and gynaecology.
- Working knowledge of:
  - Working knowledge of Trust Medicines Policy, Anaphylaxis Policy, Consent Policy and Trust protocol for Emergency Contraception
  - Evidence of continuing professional development, training and competence in supply and administration of EHC
  - Knowledge of the NMC Standards for Medicines Management 2007 [www.nmc-uk.org]

Pharmacists

- Commissioned by Devon PCT to provide Emergency Hormonal Contraception as a Locally Enhanced Service.
- The accredited Pharmacist must ensure their insurance policy includes professional indemnity cover for undertaking this service.
- Successful completion of the Centre for Pharmacy Practice (CPPE) package Emergency Hormonal Contraception (CPPE Reference: 36456)
### 3. Description of Treatment

<table>
<thead>
<tr>
<th>Name of Medicine</th>
<th>Levonorgestrel 1500 micrograms as Levonelle® 1500</th>
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<tbody>
<tr>
<td>Legal Class</td>
<td>Prescription Only Medicine (POM)</td>
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<tr>
<td>Storage</td>
<td>Store below 25°C</td>
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<tr>
<td>Dose to be used</td>
<td>One tablet containing 1500 micrograms levonorgestrel. It should be taken as soon as possible and not later than 72 hours after unprotected sexual intercourse or failed contraception.</td>
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<tr>
<td></td>
<td><strong>For women taking the contraceptive pill - see protocol</strong></td>
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<td></td>
<td><strong>For women taking liver enzyme inducing drugs – see cautions also:</strong></td>
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<tr>
<td></td>
<td>The dose should be 2 tablets, each containing 1.5 mg levonorgestrel, taken as a single dose (total dose 3mg levonorgestrel), which should be taken as soon as possible and not later than 72 hours after unprotected sexual intercourse or failed contraception. <strong>N.B. THIS IS AN UNLICENSED USE OF THIS DRUG</strong></td>
</tr>
<tr>
<td>Method or route of administration</td>
<td>Oral. The patient should be offered a glass of water and encouraged to take the dose at presentation, but this is not mandatory.</td>
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<tr>
<td>Total dose and number of times drug to be given. Details of supply (if supply made)</td>
<td>Taken as a single dose, as soon as possible and not later than 72 hours after unprotected sexual intercourse or failed contraception. See dosing schedule for patients also taking an enzyme-inducing drug.</td>
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<tr>
<td>Advice and information to patient/carer including follow-up</td>
<td>Discuss the efficacy of the emergency contraception</td>
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<td></td>
<td>Advise on future contraception. Talk through patient information leaflet with patient and supply a leaflet detailing local contraceptive services and the Family Planning Association ‘Emergency Contraception’ and ‘Your Guide to Contraception’ leaflets. Advise a follow-up at the Contraceptive Services Clinic or GP surgery.</td>
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<tr>
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<td>Advise the patient that Levonelle® 1500 can sometimes cause nausea but that vomiting is very unlikely to occur. However, if she does vomit within 3 hours of taking the medication to return to the pharmacy or seek alternative medical advice as another dose will be required immediately (providing the repeat dose is still within 72 hours of unprotected intercourse).</td>
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<td>Explain to patient that she will not be protected from pregnancy for the rest of the cycle without additional contraception (barrier methods).</td>
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<td>Explain to the patient that she may experience disruption to the timing of her next period, but if she is more than 7 days late she must have a pregnancy test.</td>
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<td>Advise patient that she may have some intermenstrual bleeding before her next period.</td>
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<td>Explain that the tablets are for emergency use only and not a regular method of contraception because it is not effective as regular contraception.</td>
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<td>Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs). Advise the patient on their exposure to STIs and give them details of local GUM services.</td>
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<td>Encourage or offer Chlamydia screening. If not offered, ensure she has details of who to contact to discuss this further.</td>
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<td>Ensure all patient counselling points on the assessment and record sheet are covered by advice and information given.</td>
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Registered Nurses, Emergency Care Practitioners (ECPs) and Pharmacists

- Should the patient wish to take the medication away with her, the patient should be issued with an original manufacturer’s pack containing one (or two as per dose criteria) tablets and a patient information leaflet. The label should contain the following – patient’s name, date of issue and directions for use, including times of doses.

- The practitioner should record the consultation by completing an assessment and record sheet, including time and date of consultation. If levonorgestrel emergency contraception is supplied then the practitioner and patient should sign only when the practitioner is confident that the client understands the information she has been given.

- For patients 18 years of age and over, the practitioner should retain the assessment and record sheets for a period of 8 years. For patients under 18 years of age, the practitioner should retain the assessment and record sheets until the patient is 25 years of age.

The following will be recorded in the patient’s clinical records (Registered Nurses and ECPs):

- The diagnosis and treatment
- The dose supplied/administered
- The route of administration
- The frequency of administration and duration of treatment
- The date of supply/administration
- The signature and name of the person administering/supplying the medication
- Whether the medication was witnessed as taken within the department

Confidentiality

All practitioners and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the patient’s consent. This duty of confidentiality applies equally to patients who are less than 16 years of age providing that child protection issues have been addressed. Practitioners should be aware of their obligations under their appropriate Code of Conduct/Ethics.

The patient should be asked if they wish their GP to be informed and supply may be communicated if consent is given.

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of June 2008 and expires end of May 2010.
## Version History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Brief Summary of Change</th>
<th>Owner’s Name</th>
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<tbody>
<tr>
<td>0.1</td>
<td>26/02/08</td>
<td>Devon PCT PGD drafted from East Devon, Mid Devon and North Devon Primary Care Trusts Patient Group Direction for the Supply of levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception (EHC) by Appropriately Registered and Qualified Practitioners Employed in Primary Care – FINAL June 2006</td>
<td>Joy Davey</td>
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<tr>
<td>0.2</td>
<td>07/04/08</td>
<td>Comments added to PGD following PGD meeting with Lisa Barnett in attendance</td>
<td>Joy Davey</td>
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<tr>
<td>0.3</td>
<td>03/06/08</td>
<td>Assessment paperwork removed from PGD (bullet point added to PGD to refer to assessment and record sheet)</td>
<td>Joy Davey</td>
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<tr>
<td>1.0</td>
<td>11/06/08</td>
<td>Final amendments made to PGD incorporating comments from PGD Group meeting.</td>
<td>Joy Davey</td>
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For more information on the status of this document, contact:

Liz Mallyon  
PA to Joy Davey (AD Medicines Management / Accountable Officer–CDs)  
Devon PCT  
Bridge House  
Brunel Industrial Estate  
Collett Way  
Newton Abbot  
TQ12 4PH  
01626 357011  
Elizabeth.mallyon@nhs.net

Date of Issue: June 2008  
Reference: PGD EHC FINAL v1.0 June08  
Path: V:\PCTs\Devon\Patient Group Directions\FINAL PDGs\EHC\PGD EHC FINAL v1.0 Jun08.doc
The registered Nurses, Emergency Care Practitioners And Named Community Pharmacists named below, being employees of Devon Primary Care Trust or employed by ______________________ practice / pharmacy at ______________________ are authorised to administer / supply levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception (EHC) by Appropriately Registered and Qualified Practitioners as specified under this Patient Group Direction

I agree to administer/supply the above preparation in accordance with this Patient Group Direction:

<table>
<thead>
<tr>
<th>NAME</th>
<th>TITLE</th>
<th>SIGNATURE</th>
<th>AUTHORIZING MANAGER</th>
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Keep original with authorising manager and send a copy to:

Joy Davey – Assistant Director, Medicines Management & Accountable Officer – Controlled Drugs
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