# CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR EMERGENCY HORMONAL CONTRACEPTION Levonorgestrel 1500mcg

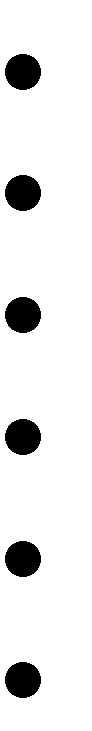
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| **Staff Characteristics** | |
|  | Community pharmacists authorised by Stoke-on-Trent City Council via Tier 1 service (clients aged 16+) or Tier 2 service (including clients under the age of 16 years) |

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| **Clinical Details** | |
| **Indication** | Emergency Contraception |
| **Aims** | To reduce the number of unwanted pregnancies in  Stoke-on-Trent by the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist. |
| **Inclusion Criteria** | 1. The client presents within 72 hours of having   sexual intercourse without using contraception or thinks their method of contraception may have failed i.e. Unprotected sexual intercourse, barrier/condom failure, missed pills (refer to current BNF), IUD expulsion, severe diarrhoea and vomiting which may have reduced oral contraception efficacy, allowed >89 days to elapse since the last medroxyprogesterone injection.   1. Client has received Levonorgestrel 1500mcg under PGD but has vomited within 2 hours\* of the dose (provided still within 72 hours of sexual intercourse). (\*Use outside product licence – product licence states within 3 hours, this PGD is based on WHO/Faculty of Sexual and Reproductive Health (FSRH) recommendations and is consistent with good practice recommendations in the UK) 2. The client is either unable or does not wish to attend other local agencies and is willing to accept the limited service available through the pharmacist. Clients will always be offered information regarding access to comprehensive contraception and sexual health services available locally. |

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|  | Under the terms of this PGD it is not possible to give  EHC to women as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party. |
| **Exclusion Criteria** | 1. If more than 72 hours after unprotected   intercourse.   1. Client is aged 13 years and under. 2. The client is already pregnant or they think they may be pregnant. 3. The clients last period was late or last period was unusual. (not explained by current hormonal contraception e.g. Cerazette, Depo-Provera) 4. The client is suffering from abnormal vaginal bleeding. (not explained by current hormonal contraception e.g. Cerazette, Depo-Provera) 5. The client has any known hypersensitivity to the active substance levonorgestrel or any of the excipients. 6. The client is deemed not to be Gillick Competent as defined in the Fraser Guidance 1985. 7. Active Acute Porphyria   9. Patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy. |
| **Management of**  **excluded clients** | * If the client falls into the above Exclusion Criteria, Levonorgestrel 1500mcg cannot be issued. * If client is more than 72 hours but less than 120 hours after unprotected intercourse consider issuing Ulipristal Acetate via PGD. * If client wishes an emergency IUD please refer to Cobridge Integrated Sexual Health Clinic. |
| **Criteria for possible referral** | 1. The client is currently suffering from severe liver disease. 2. The client currently has breast cancer. 3. The client suffers from Crohn’s Disease or other severe malabsorption syndrome. 4. Currently taking interacting drugs: rifampicin, carbamazepine, ciclosporin, warfarin, griseofulvin, primidone, phenobarbital, phenytoin, topiramate, ritonavir, St.Johns Wort – refer to BNF for full list. N.B. A copper intrauterine device is the preferred option in these women. 5. The client is aware of any other medical reason why she should not take emergency contraception (Levonorgestrel 1500mcg) these include: severe hypertension, diabetes mellitus with   nephropathy, retinopathy or vascular disease, ischaemic heart disease, stroke, past history of |

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|  | breast cancer. Hereditary problems of galactose intolerance, Lapp lactase deficiency.  If the client has any of the above medical conditions or takes the medication listed above the pharmacist should explain that the risk of pregnancy are almost certainly greater than those associated with taking Levonorgestrel 1500mcg and proceed as appropriate. If the client suffers from a malabsorption syndrome or is taking an enzyme inducer if possible she should be referred to a GP or Contraceptive and Sexual Health (CASH) clinic where a double dose of Levonorgestrel 1500mcg may be prescribed. This is not possible under the Patient Group Direction. The client should also be informed of non-drug alternatives such as an IUD. |
| **Management of**  **patients requiring referral** | Advise patient of alternative sources of treatment.  Refer to their GP, a Contraceptive and Sexual Health (CASH) clinic or Hanley Health and Well Being Centre. |

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| **Drug Details** | |
| **Name, form & strength of medicine** | Levonorgestrel 1500 microgram tablet |
| **Legal classification** | Prescription Only Medicine (POM) |
| **Route/Method** | Oral |
| **Dosage/Frequency/**  **Duration of Treatment** | One tablet of 1500 micrograms as a single dose as  soon as possible, preferably within 12 hours and no later than 72 hours after unprotected intercourse. Only 1 dose in any single menstrual cycle, as levonorgestrel can cause disturbance of subsequent cycles.  Levonorgestrel 1500mcg can be used more than once in a cycle if clinically indicated. i.e. if patient vomits within 2 hours of taking the dose, a replacement supply should be issued, as long as the dose remains within 72 hours of the episode of UPSI (see local policy). |
| **Quantity to**  **supply/administer** | 1 tablet (1 pack) Patients taking enzyme inducers –  seek medical advice. |



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| **Cautions** | **Potential drug interactions:**  The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers.  Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John’s Wort), rifampicin, ritonavir, rifabutin, griseofulvin.  Medicines containing levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.  **Please refer to current BNF** [**http://bnf.org/bnf/**](http://bnf.org/bnf/) **and SPC for full details** [**http://www.medicines.org.uk/emc/**](http://www.medicines.org.uk/emc/)  **Pregnancy**  If pregnancy occurs after treatment with levonorgestrel, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. |
| **Side Effects** | Patient may experience:  Nausea and vomiting Breast tenderness Headache  Dizziness Fatigue  Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time. If the  next menstrual period is more than 5 days overdue, pregnancy should be excluded.  **Please refer to current BNF** [**http://bnf.org/bnf/**](http://bnf.org/bnf/) **And SPC for full details** [**http://www.medicines.org.uk/emc/**](http://www.medicines.org.uk/emc/)  Use the Yellow Card System to report adverse drug reactions directly to the MHRA. Yellow Cards and guidance are available at the back of the BNF. [**http://yellowcard.mhra.gov.uk/**](http://yellowcard.mhra.gov.uk/) |

**Advice to patients**

* Patient Information Leaflets should be

highlighted and given to all women supplied with Levonorgestrel 1500mcg emergency contraception.

* Local guide to Contraceptive and Sexual Health (CASH) services.
* Clients who vomit or have severe diarrhoea within 2 hours\* of taking Levonorgestrel 1500mcg tablet should be advised to return to the pharmacy or visit their GP or CASH clinic. If the replacement dose would be later than 72 hours after unprotected intercourse, referral for an IUD/Ulipristal Acetate may be indicated and the tablets should not be issued.
* Advise client that her period may arrive earlier, on time or later than usual, that her period may be lighter or heavier and that this supply only treats this episode of unprotected intercourse.
* If further unprotected intercourse occurs in that menstrual cycle, advise client that CASH service may be able to issue further supplies or fit an IUD
* Clients who have no period within 3 weeks of taking Levonorgestrel 1500mcg or if the next period is more than 7 days late or abnormal in any way should go to their GP or Contraceptive and Sexual Health (CASH) clinic to check they are not pregnant.
* Emphasise that these tablets are for emergency use only and not as a regular method of contraception, because it is not as effective as regular contraception. Advise that use of emergency contraception does not replace the necessary precautions against sexually transmitted infections.
* If any abnormal bleeding or pain in days following taking Levonorgestrel 1500mcg the client should be advised to contact her GP. The overall risk of ectopic pregnancy following Levonorgestrel 1500mcg does not appear to be increased; however case reports of such incidents have been documented. There is insufficient post-marketing data to allow accurate assessment of risk. Clinicians and women should be alert to marketing the possibility but the risk is likely to be small.
* Clients who receive Levonorgestrel 1500mcg emergency contraception should be advised to visit either a GP or Contraceptive and Sexual Health (CASH) clinic to discuss their further contraceptive needs. Contraception can now be “quick started” following EHC i.e. started immediately rather than waiting until next period.
* If client is on the oral contraceptive pill, then this should be taken again within 12 hours of taking Levonorgestrel 1500mcg. Condoms should be used for any intercourse within the next 7 days if using combined oral contraceptive pill, or for 2 days if using progestogen only pill.
* Advise clients taking oral diabetic drugs and insulin that they may find their sugar levels change due to taking Levonorgestrel 1500mcg, but for a short time only.

**Please refer to current BNF** [**http://bnf.org/bnf/**](http://bnf.org/bnf/) **or**

**SPC for full details** [**http://www.medicines.org.uk/emc/**](http://www.medicines.org.uk/emc/)

## Information to clients before supply

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| Mode of Action | Unknown but thought to work by preventing ovulation and  fertilisation by altering tubal transport of sperm and/or ova. It may also cause endometrial changes that discourage implantation. This means it stops pregnancy before it starts. | |
| Risks | **Coitus-to-treatment interval** | **Percentage of expected** |
|  | **pregnancies prevented** |
| 24 hours or less | 95% |
| 25 – 48 hours | 85% |
| 49 - 72 hours | 58% |
| Results from a recent clinical study showed that a 1500  microgram single dose of Levonorgestrel 1500mcg (taken within 72 hours of unprotected sex) prevented 84% of expected pregnancies (compared with 79% when the two 750 microgram tablets were taken 12 hours apart). | |
| If the assessed risk of pregnancy is high (20-30%), the  residual risk after Levonorgestrel 1500mcg may remain unacceptably high for some women. The option of an IUD with its low failure rate may be appropriate even if the woman presents within 72 hours. In such cases Levonorgestrel 1500mcg may still be supplied under the PGD. | |
| If already pregnant | If pregnancy is not prevented consensus of opinion is that  Levonorgestrel 1500mcg emergency contraception will not have an effect on the foetus. However a normal pregnancy as in any other situation cannot be guaranteed. | |
| Adverse effects | * Nausea in up to 1 in 7 women and 1 in 100 actually sick   Client should be advised to return if they vomit within 2 hours\* of taking the dose because the treatment will not be effective and they should obtain an additional supply  Changes to pattern of menstrual bleeding (period may be early or late)  If fails – risk of ectopic pregnancy, advise client to contact GP/ Family Planning to ensure it is not ectopic   * Occasionally tender breasts, headaches, dizziness or tiredness | |

Until next period Pharmacist to stress that this only provides contraception for one episode. Clients need to either abstain from sexual intercourse or use barrier method for the remainder of the cycle unless currently using oral contraception (refer to section – advice to parents).

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| Records and Follow Up | | |
| Supply | Clients are required to take Levonorgestrel 1500mcg in the pharmacy. They should be provided with the patient information leaflet and local guide to Contraceptive and Sexual Health (CASH) services.  Cobridge Clinic 0300 7900 165  [www.staffordshireandstokeontrent.nhs.uk/services/cash.htm](http://www.staffordshireandstokeontrent.nhs.uk/services/cash.htm)  All clients whether supplied with EHC or not should be given the local guide to Contraceptive and Sexual Health (CASH) services | |
| **Records/audit trail** | * In discussion with the client complete the proforma. * If Levonorgestrel 1500mcg emergency contraception is supplied then the pharmacist asks the client to sign only when the pharmacist is confident that the client understands the information she has been given.   Patient records and the completed proformas should be retained for adults for a period of 10 years after attendance and for children until the child is 25 years old. Computerised patient medication records are recommended to be kept. | |
| **Adverse drug reactions** | All serious adverse reactions must be reported to  MHRA via the yellow card system [**www.yellowcard.gov.uk**](http://www.yellowcard.gov.uk/). A client presenting with a suspected serious ADR should be referred to their GP. | |
| **Date last reviewed: March 2014** | | **Date for next review:** |
| **Expiry date:** | | **Ref Code:** |

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| **References** | **BNF – Current Version 2013**  **SPC Levonelle 1500 – Bayer Healthcare September 2012**  **PIL Levonelle 1500 - Bayer Healthcare September 2012**  **FSRH – Clinical Guidance Emergency Contraception 2012** |
| **Glossary** | **BNF – British National Formulary**  **SPC – Summary of Product Characteristics PIL – Patient Information Leaflet**  **PGD – Patient Group Direction**  **FSRH – Faculty Sexual & Reproductive Health** |