NHS Borders

# Patient Group Direction for the supply and/or administration of Cerazette (Desogestrel 75 micrograms) to women requesting contraception attending NHS Borders Sexual Health Clinics.

This document authorises the supply or administration of Cerazette (Desogestrel 75 micrograms) by Sexual Health Nurses to women requesting contraception who meet the criteria for inclusion under the terms of the document

The Sexual Health Nurses seeking to supply or administer Cerazette (Desogestrel 75 micrograms) must ensure that all patients have been screened and meet the criteria before supply takes place

The purpose of this Patient Group Direction is to ensure access to contraception without the presence of a Sexual Health doctor

This direction was authorised on: June 2011

The direction will be reviewed by: June 2013

Clinician Responsible for Training and Review: Clinical Lead for Sexual and reproductive Health

PGD developed/reviewed by: Dr Ailsa Wylie, Liz Leitch, Gillian Forbes and Gavin Gorman

**Patient Group Direction for the supply and/or administration of Cerazette (Desogestrel 75 micrograms) without a prescription for a named individual by Sexual Health Nurses employed by NHS Borders in Borders Sexual Health Clinics**

**1. This Patient Group Direction relates to the following specific preparation:**

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| Name of medicine, strength, formulation | Cerazette (Desogestrel 75 micrograms) tablets |
| Legal status | Prescription Only Medicine (POM) |
| Storage | In a locked drug cupboard |
| Dose | One tablet |
| Route/method | Oral |
| Frequency | Once daily, continuously at the same time at each day. |
| Total dose Quantity (Maximum/Minimum) | Max 3/12 supply at first visit, thereafter 6/12 supply. 12 month supply may be issued thereafter, if patient has met criteria. |
| Advice to Patients | • Mode of action<br>• Method of taking. To be taken at the same time each day, starting on day 1 of cycle then continuously. If starting day 2 – 5 during first cycle a barrier method is recommended for the first two days of tablet taking<br>• Efficacy, advantages and disadvantages including minimal increased risk of breast cancer<br>• 2 day rule, missed pill advice – especially if administration delayed for 12 hours or more<br>• Safe sex<br>• Manufacturers information leaflet should be given.<br>• Side effects: cycle irregularity, amenorrhoea, irregular bleeding in up to 50% of users, acne, breast pain, mood changes, chloasma, gastrointestinal symptoms, rash, headache, migraine, hypertension, depression, fatigue, nervousness, weight increase and loss of libido.<br>• In contrast to traditional progestogen only |

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| | preparations the contraceptive efficacy of Cerazette is achieved by the inhibition of ovulation. Advise women to contact nurse/GP if they experience adverse effects. If they experience amenorrhoea within the first two months and are worried that they might be pregnant they should obtain a pregnancy test.<br>• Advise that risk of coronary artery disease when taking oral contraceptive is increased by cigarette smoking, hypercholesteroleamia, obesity, diabetes, history of pre-eclampsic toxaemia and increasing age. |
| Follow up Arrangements | As directed by a medical or non medical prescriber (it is ***strongly*** recommended that the woman is seen by a medical or non medical prescriber before either the first or second supply of Cerazette).<br>After being seen at first or second visit by a medical or non medical prescriber the woman can be seen by a nurse for a maximum of 21 months and must then be assessed by a doctor. |
| Relevant Warnings | • All adverse drug reactions should be reported to Clinical Service Manager.<br>• Advise women with diabetes that a decrease in glucose tolerance may result.<br>• Treatment with Cerazette® leads to decreased serum oestradiol levels – it is as yet unknown as to whether the decrease has a clinically relevant effect on bone mineral density. |

**2. Clinical condition**

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| Clinical Condition to be treated | As progestogen only contraception for appropriately assessed women. |
| Criteria for inclusion | • Use of cerazette is restricted to use in women who either cannot tolerate oestrogen-containing contraceptives or in whom they are contra-indicated.<br>• Cerazette may be an appropriate choice for less compliant women (including younger women), due to continued contraceptive protection for up to 12 hours after missing a dose of cerazette (3 hours for other Progestogen Only Pills-POP)<br>• Cerazette may be an appropriate choice for |

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| | women taking a POP who have a history of ectopic pregnancy<br>• 14-50 years |
| Criteria for inclusion Special consideration for off licence use | **"Quick starting" contraception is regarded as accepted practice and supported by the Faculty of Sexual & Reproductive Health – FSRH. Please refer to the FSRH CEU Guidance.** "Quick Starting Contraception" Sept 2010.<br>**If the POP is prescribed 'outside its product license', this must be discussed with the patient and documented in the clinical record.**<br>a) Please refer to the Faculty of Sexual & Reproductive Health – FSRH CEU "Cerazette – Desogestrel only pill" April 2003 for full details on recommended starting routines.<br>b) Starting the POP immediately following hormonal emergency contraception (Levonelle) – also referred to as 'quick-starting': The FSRH considers this practice as reasonable if abstinence is unlikely or further condom failure a possibility. Reassuringly, no hormonal method has been shown to be associated with an increased risk of fetal abnormality and the POP can be discontinued should Levonelle fail and a pregnancy occur.<br>If the POP is started at the time of giving Levonelle the client should be advised that additional barrier contraception is required for 7 days and that a pregnancy test should be performed in 3 weeks. The decision to start the POP immediately following hormonal emergency contraception (Levonelle) should be made on an individual basis and in discussion with the client.<br>See CEU guidance "Quick Starting Contraception" Sept 2010. |
| Criteria For Exclusion | Women aged under 14 years and 50 years and over<br>• Known or suspected pregnancy<br>• Progestogen dependent tumours e.g. history of breast cancer, genital or hormone dependent cancer<br>• Acute, severe chronic or active liver disease; recurrent cholestatic jaundice or liver tumours<br>• History of jaundice in pregnancy or with previous contraceptive pill use<br>• Active venous thromboembolic disorder<br>• Unexplained abnormal vaginal bleeding |

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| | • History of ischaemic heart disease<br>• History of cerebrovascular accident<br>• Hypertension – BP more than 160/95<br>• Malabsorption syndromes<br>• History of functional ovarian cysts<br>• Onset of focal migraine for the first time while taking Progestogen only contraception<br>• Porphyria<br>• Following evacuation of hydatidiform mole<br>• Use of St John's Wort<br>• Use of rifampicin, griseofulvin, phenytoin, carbamazepine, barbiturates, primidone, oxycarbazepine, rifabutin, ritonavir and medical charcoal.<br>• Informed non consent<br>• Hypersensitivity to Desogestrel (Cerazette)<br>• Long term immobilizations (including elective surgery)<br>• Assessed as not competent to consent to treatment (apply Fraser Guidelines to under 16s). |
| Action if excluded | Refer to clinic doctor. |
| Action if declines | Offer suitable alternative.<br>Refer to clinic doctor. |
| Interactions with other medicaments and other forms of interaction | Advise women that pregnancies have been reported in women taking oral contraceptives concurrently with rifampicin and other enzyme inducing antibiotics, some HIV drugs, anti-epileptic drugs, barbiturates and other sedative drugs. |

**3. Records - Kept in a locked cupboard at Sexual Health Clinic**

**a) The following records should be kept (either paper or computer based)**

The GP practice, clinic, hospital, and ward or department
The patient name and CHI number
The medicine name, dose, route, time of dose(s), and where appropriate, start date, number of doses and or period of time, for which the medicine is to be supplied or administered
Drug batch number and expiry
The signature and printed name of the approved healthcare professional who supplied or administered the medicine
The patient group direction title and/or number
Whether patient met the inclusion criteria and whether the exclusion criteria were assessed
Quantity supplied / received and current stock balance

**b) Preparation, audit trail, data collection and reconciliation**

Stock balances should be reconcilable with receipts, administration, records and disposals on a patient by patient basis.

**c) Storage** - In a locked drug cupboard

Standards must be consistent with the Summary of Product characteristics.

## 4. Professional Responsibility – Registered Nurses and Midwives with Family Planning Certificate of Competence.

- All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of this medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate. For those involved in immunization, regular anaphylaxis updates are mandatory.

- Nurses will have due regard for the NMC Code of Professional Conduct, standards for conduct, performance and ethics (2008) and NMC Standards for Medicines Management (2008)

## 5. References


- British National Formulary (BNF) current edition http://bnf.org/bnf/index.htm

- Borders Joint Formulary (BJF) http://intranet/new_intranet/microsites/index.asp?siteid=65&uid=1

- WHO Medical Eligibility Criteria for Contraceptive Use from the Faculty of Family Planning and Reproductive Healthcare of the Royal college of Obstetricians and Gynaecologists. If no paper copy available can be sourced on Faculty Sexual and Reproductive Healthcare website. www.fsrh.org

- SPC Cerazette (Desogestrel 75 micrograms) http://www.medicines.org.uk/EMC/medicine/10098/SPC/Cerazette+75+microgram+film-coated+tablet/

**Patient Group Direction for supply and/or administration of Cerazette (Desogestrel 75 micrograms) by Sexual Health Nurses employed by NHS Borders**

| This Patient Group Direction is approved for use by the under-signed : | | | |
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| **Job Title** | **Name** | **Signed** | **Date** |
| **Senior Doctor/Dentist for relevant clinical area** | Dr Ross Cameron | | 21/6/11 |
| **NHS Borders Director of Pharmacy** | Mrs Alison Wilson | | 22/6/11 |
| **NHS Borders Senior Health Professional for Clinical Area** | Mrs Sheena Wright | | 22/6/11 |
| **PGD AUTHORISED ON** 23/6/11<br>**Signed by ADTC CHAIRPERSON:** .....<br>**Name:** ...John Hammond..... | | | |

**The Health Professionals named below, being employees of NHS Borders are authorised to provide and/or administer this medication under this Patient Group Direction and agree to provide and/or administer this medication in accordance with this Patient Group Direction**

| Name of Health Professional | Job Title | Signed | Date |
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