Patient Group Direction (PGD) for

Supply of **Cilest® (Norgestimate 250micrograms Ethinylestradiol 35micrograms)** for **contraception** by registered nurses employed by NHS Rotherham community health services working within Contraception and Sexual Health Services (CASH) who are CASH trained, have received appropriate training on the supply of Cilest® and are deemed competent to supply.

<table>
<thead>
<tr>
<th>PGD Number:</th>
<th>FP26</th>
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<tbody>
<tr>
<td>Author:</td>
<td>Janet Casswell (CASH nurse)</td>
</tr>
<tr>
<td>Head of Services:</td>
<td>Jean McVann</td>
</tr>
<tr>
<td>Discipline:</td>
<td>CASH (Contraception and Sexual Health)</td>
</tr>
<tr>
<td>Date Sent to Non-prescribing Procedure Advisory Group:</td>
<td>25 June 09</td>
</tr>
<tr>
<td>Date Ratified at Prescribing Committee:</td>
<td>1st July 2009</td>
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<tr>
<td>Date of Next Review:</td>
<td>1st July 2011</td>
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<tr>
<td>Dissemination:</td>
<td>Jean McVann</td>
</tr>
<tr>
<td>Implementation:</td>
<td>Jean McVann</td>
</tr>
<tr>
<td>File Location:</td>
<td>Prescribing &amp; Medicines Management with link to policies and procedures</td>
</tr>
<tr>
<td>Key Words:</td>
<td>Cilest® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) PGD, CASH</td>
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<tr>
<td>Date Uploaded &amp; By Whom:</td>
<td>01 July 2009</td>
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This Patient Group Direction is operational from 01/07/2009 and will be reviewed every 2 years or in the light of new national guidance.
Patient Group Directions are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration under a PGD should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

- Each PGD has a unique identifier allocated by the Prescribing Adviser responsible for the management of Patient Group Directions for the organisation.
- Once a PGD has been given approval, the date on which the PGD comes into effect will be inserted by the Prescribing Adviser prior to submission onto the NHS Rotherham intranet.
- The PGD must be reviewed within two years of authorisation
- PGDs that have failed to be reviewed and re-ratified must not be used past their expiry date and patient specific direction (prescriptions) must be used to authorise supply of medicines.

All of the following information must be completed in full:

| Supply of Cilest ® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) for contraception by registered nurses employed by NHS Rotherham community health services working within Contraception and Sexual Health Services (CASH) who are CASH trained, have received appropriate training on the supply of Cilest® and are deemed competent to supply. |

1. Clinical Condition or situation to which the direction applies

Drug Name: Cilest ® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) Tablets

<table>
<thead>
<tr>
<th>Clinical Indications</th>
<th>Contraception</th>
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<tr>
<td>Patients over 16 years ( &amp; between 13 and 16 years who are deemed to be competent under Fraser guidelines) Until one year after menopause (or two years if under 50) Requesting first supply of combined oral contraception (Only to be used first line if client suffers from PMS symptoms in line with GREEN TOP guidelines, or suffering with skin conditions) Requesting repeat supplies of combined oral contraception (COC) Heavy Painful periods</td>
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</table>

UNLICENSED INCLUSIONS:
- Women requiring ongoing contraception where standard tablet taking has resulted in a failure of the method and where no alternative method is acceptable
- Women wanting ongoing contraception to start immediately following emergency contraception, where it is assessed that additional risks of conception may occur

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### Patient Group Direction No. FP26

**Criteria for Exclusion**

- Known allergy to any of the ingredients of these medications
- Pregnancy or suspected pregnancy
- Breast feeding
- Unexplained vaginal bleeding
- Current or History of breast, lung or genital tract cancer
- Liver disease including hepatitis
- Acute porphyria
- Systemic lupus erythematosus
- COC or pregnancy related jaundice, pruritis or chorea or deterioration of otosclerosis, pemphigoid gestationis
- Gallbladder disease
- Recent Hydatidiform mole
- Severe malabsorption (eg Crohn's disease)
- Within 4 weeks of major surgery
- Current or history of thromboembolic disorders or stroke in patient or first degree relative
- Valvular heart disease
- Known hyperlipidaemia
- Diabetes with vascular complications
- Sickle cell anaemia
- Focal migraine
- B/P above 140/90
- BMI of 35 or above
- BMI of 30 or above and smoking more than 15 per day
- Smokers aged 35 years plus
- Patients more than one year past menopause (or two years if under 50)
- Heart disease associated with pulmonary hypertension or risk of embolus
- History of Transient Ischaemic Attack
- Undiagnosed vaginal bleeding
- Severe renal insufficiency or acute renal failure
- Presence or history of liver tumours (benign or malignant)
- Taking warfarin or ciclosporin

**Action if Excluded**

- If any criteria for exclusion applies
- If a patient under 16 years is not deemed to be competent under Fraser guidelines
- Offer alternative methods or seek advice from the clinic Doctor
- Record in patient record

**Action if Patient declines Treatment**

- Advise patient of risks of pregnancy
- Advise patient of use of alternative contraception and availability
- Record in patient record

**Notes for doctors / drug interactions**

- Broad spectrum antibiotics may reduce contraceptive efficacy of combined oral contraceptives (COC)
- COC may affect requirements for oral antidiabetic medication and insulin
- COC may alter the effect of warfarin
- COC may inhibit ciclosporin metabolism leading to ciclosporin toxicity
- The effectiveness of combined oral contraception may be reduced by the following liver enzyme inducing
This Patient Group Direction is operational from 01/07/2009 and will be reviewed every 2 years or in the light of new national guidance.

<table>
<thead>
<tr>
<th>Name, strength and formulation of drug</th>
<th>Cilest ® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) Tablets</th>
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<tbody>
<tr>
<td>Legal status</td>
<td>POM</td>
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<tr>
<td>Storage</td>
<td>Store below 25 °C or in accordance with the manufactures instructions</td>
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<tr>
<td>Dose/dose range</td>
<td>1 tablet</td>
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</tbody>
</table>

2. Description of treatment

Drug Name: Cilest ® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) Tablets

<table>
<thead>
<tr>
<th>medication. Referral to a doctor is therefore recommended if any of the following are being taken:</th>
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<tbody>
<tr>
<td>Phenytoin</td>
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<td>Barbiturates</td>
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<td>Primidone</td>
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<td>Carbamazepine</td>
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<td>Oxcarbamazepine</td>
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<td>Rifampicin</td>
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<td>Rifabutin</td>
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<td>Ritonavir</td>
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<td>Griseofulvin</td>
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<td>Modafinil</td>
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<td>Nelfinadir</td>
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<td>Nevirapine</td>
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<td>Topiramate</td>
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<td>St Johns Wort</td>
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</table>

This list may not be exhaustive and medication should be checked in the current BNF.

POTENTIAL SIDE EFFECTS

- Nausea and vomiting
- Breast tenderness
- Headaches
- Weight gain or loss
- Fluid retention
- Changes in libido
- Depression
- Thrombosis
- Chorea
- Skin reaction
- Chloasma
- Hypertension
- Liver function impairment
- Hepatic tumours
- Reduced menstrual loss
- Vaginal spotting in early cycles
- Absence of withdrawal bleed
- Photosensitivity
- Increased risk of breast cancer

This document expires on 01/07/2011
<table>
<thead>
<tr>
<th>Method /route</th>
<th>oral</th>
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</table>
| Frequency of administration | Daily at the same time each day, starting on Day 1 of menstrual cycle, for 21 days, followed by a 7 day tablet free interval.  

**UNLICENSED USES**  
Women requiring ongoing contraception where standard pill taking has resulted in a failure of the method and where no alternative method is acceptable - daily starting on day 1 of menstrual cycle for 21 days, followed by a 4 day tablet free interval.  

Women wanting ongoing contraception to start immediately following emergency contraception, where it is assessed that additional risks of conception may occur - daily starting immediately for 21 days, followed by a 7 day tablet free interval. |
| Total dose number | One packet – 21 tablets  

**TOTAL QUANTITY TO BE SUPPLIED:**  
Ongoing contraception  
x 2 or 3 packs for first issue (in line with first issue guidelines)  
x 6 packs for repeat issue  
up to 3 packs for repeat issue (if BMI close to cut off or any other health concerns that need monitoring & document in record)  
1 TABLET DAILY |
| Patient/carer advice and follow-up treatment | Explanation of  
• Mode of action  
• Efficacy  
• Possible side effects, risks and benefits  

To use a barrier method of contraception if a tablet is missed or is more than 12 hours late. In addition, if the missed tablet is in the last seven of the pack, the next pack of tablets should be started immediately after finishing the current pack, without having a tablet free interval.  

To use a barrier method of contraception for the duration of, and for 7 days after, if diarrhoea or vomiting occurs or taking a broad spectrum antibiotic  

When to start taking the first pack of pills  

To stop the pill immediately and seek urgent medical help if any of the following develop:  
• Sudden severe chest pain  
• Sudden breathlessness  
• Coughing blood |
• Severe pain in one calf
• Severe stomach pains
• Serious neurological effects such as loss of vision, hearing or speech, numbness or weakness of a part of the body
• Unusual severe prolonged headache

ADDITIONAL INFORMATION TO GIVE FOR UNLICENSED USE

Explore other options including LARC and coil
Inform the patient that the medication is being used outside its license
Give full explanation of why the product is not licensed for this use
Ensure the directions for taking the medication are understood, as they may contradict standard written instructions

Women wanting ongoing contraception to start immediately following emergency contraception, where it is assessed that additional risks of conception may occur
ADVISE PREGNANCY TEST IN 3 WEEKS

Women who are taking interacting medication—
Advise nature of interaction
Advise appropriate monitoring

3. Records

1. The following records should be kept either paper or computer based
For all vaccinations, the following information should be entered on all manual records including the Personal Child Health Record (PCHR-red book), computerised records and data collection for Child Health Information Services (CHIS):

   Records should be kept at Family Planning and information passed to patient and GP with consent.
   • Complete Record of Attendance documentation and if appropriate enter on record ‘Protocol fulfilled’
   • Patient’s name, address, date of birth and consent given
   • Diagnosis
   • Name of medication
   • Dose given.
   • Brand, Batch Number and Expiry Date (if supplied)
   • Signature & name of staff who administered or supplied the medication, and also, if relevant, signature & name of staff who removed/discontinued the treatment
   • Route and site of administration (record all sites of administration to allow any reactions to be related to the site of the injection
   • Contact details of GP (if registered)
   • Information & advice given to patient (including side effects)
   • Details of any adverse drug reaction and actions taken, including documentation in the patient’s medical record. Any adverse reaction must be notified to GP.
   • Referral arrangements (including self care)
2. Audit Trail Data Collection

- A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each practice/service.
- **Reconciliation**: Stock balances should be reconcilable with Receipts, Administration, Records and Disposals on a patient-by-patient basis
- **Storage**: Standards must be consistent with the Summary of Product Characteristics. All medication must be stored in a secure locked environment away from the direct patient care area

3. Anaphylaxis - Emergency Treatment

Before administering any medication the possibility of anaphylaxis must be discussed and documented with the patient/carer prior to administration of any medication, which may produce an anaphylactic reaction.

When giving any medication the following should always be readily available:
- Access to the patients notes
- Adrenaline (Epinephrine) 1 in 1000 for intramuscular (i.m.) injection for use in emergency (NB: **check expiry dates** regularly)
- Syringes and needles of *suitable size* and capacity for dose.
- Patient Group Direction for the Administration of Adrenaline (Epinephrine) 1 in 1000.
- Access to a telephone

**PLEASE BE AWARE OF RESUSCITATION COUNCIL GUIDELINE CHANGES – Jan 2008.**

<table>
<thead>
<tr>
<th>Adrenaline (Epinephrine) 1 in1000 (1mg/ml)</th>
<th>For intramuscular injection</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>Dose</td>
</tr>
<tr>
<td>Children under 6 years</td>
<td>150 micrograms</td>
</tr>
<tr>
<td>Children 6 – 12 years</td>
<td>300 micrograms</td>
</tr>
<tr>
<td>Adults and adolescents</td>
<td>500 micrograms</td>
</tr>
</tbody>
</table>

These doses may be repeated if necessary at 5-minute intervals according to blood pressure, pulse and respiratory function.

Special cautions: see BNF 3.4.3

Epinephrine/ Adrenaline

BNF (56th edition) section 3.4.3 page 170-171

(Updated Jan 2008)
5. Professional Responsibility

All practitioners

- The practitioner will ensure he/she has the relevant training and is competent, including contraindications. He/she will attend training updates as appropriate. **Details of the competency programme developed for use with this PGD must be attached (see PGD process above).**
- The practitioner will have due regard for the their Professional Conduct and Guidelines for the Administration / Supply of Medicines
- It is the responsibility of the individual practitioner to ensure that he/she has appropriate knowledge of the product prior to proceeding. Refer to the Summary of Product Characteristics (SPC) or current BNF for further details on the product.
- Each individual must have received a personal copy of the PGD and signed on the list of individual professionals who may work within this PGD (kept with master copy of this PGD)
- Must be competent in the recognition and management of anaphylaxis.
- Must have access to all relevant DH advice, including the relevant CMO letters or training and competent in all aspects of immunisation including contraindications and recognition and treatment of anaphylaxis where appropriate.
- Must have access to a current copy of the BNF and *Immunisation against infectious disease* (The ‘Green book’) and comply with its recommendations (available on DH website – [www.dh.gov.uk/greenbook](http://www.dh.gov.uk/greenbook)) where appropriate.
- Annual attendance at the NHS Rotherham’s or workplace update on resuscitation skills and the management of anaphylaxis within the community.
- Maintenance of own level of updating with evidence of continued professional development (PREP requirements).
- Regular updates in immunisation, vaccination, anaphylaxis and cardiopulmonary resuscitation where appropriate.
- To reinforce and update knowledge and skills in this area of practice, including basic resuscitation and anaphylaxis training, with particular reference to changes and national directives.
- Such practitioners that meet the above criteria for training have NHS Rotherham approval to administer/supply **Cilest® (Norgestimate 250micrograms Ethinylestradiol 35micrograms) Tablets** in accordance with this PGD without a doctor’s prescription, and with the patient’s informed consent.
- Storage and handling of medicines should be carried out accordance with NHS Rotherham’s Medicines Policy.
- The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicine, including those supplied under Patient Group Directions and all products other than those immediately administered must be labelled for supply to patients.


Other reference sources.
6. Management of Patient Group Direction

This patient group direction is to be read, agreed to and signed by all healthcare professionals to whom it applies. One copy should be given to each practitioner with the original signed with a copy being kept by the nominated doctor with responsibility for PGDs within the organisation.

<table>
<thead>
<tr>
<th>Developed by:-</th>
<th>Name &amp; Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepared and approved by:</td>
<td>Janet Casswell</td>
<td>Janet Casswell</td>
<td></td>
</tr>
<tr>
<td>Name and title in block capitals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lead doctor/dentist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consultant in area concerned</td>
<td>Rupasree Tewari</td>
<td>Rupasree Tewari</td>
<td></td>
</tr>
<tr>
<td>Name and title in block capitals</td>
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</tr>
<tr>
<td>Lead pharmacist</td>
<td>Eloise Summerfield</td>
<td>Eloise Summerfield</td>
<td></td>
</tr>
<tr>
<td>Lead health professional from group who will administer/supply medicine</td>
<td>Jean McVann</td>
<td>Jean McVann</td>
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</tbody>
</table>

Supply of *Cilest® (Norgestimate 250micrograms Ethinylestradiol 35micrograms)* for contraception by registered nurses employed by NHS Rotherham community health services working within Contraception and Sexual Health Services (CASH) who are CASH trained, have received appropriate training on the supply of Cilest® and are deemed competent to supply.

This Patient Group Direction for use in NHS Rotherham is authorised by us

<table>
<thead>
<tr>
<th>Job Title</th>
<th>Name</th>
<th>Signed</th>
<th>Date</th>
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</thead>
<tbody>
<tr>
<td>Director of Public Health</td>
<td>John Radford</td>
<td>John Radford</td>
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<tr>
<td>Medical Director</td>
<td>David Plews</td>
<td>David Plews</td>
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<tr>
<td>Prescribing &amp; Pharmaceutical Adviser</td>
<td>Sue Wright</td>
<td>Sue Wright</td>
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<tr>
<td>Head of Service</td>
<td>Jean McVann</td>
<td>Jean McVann</td>
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Patient Group Direction No. FP26

The registered nurses named below, being employees of
NHS Rotherham Community Health Services based at the family planning
are authorised to supply Cilest ® (Norgestimate 250micrograms Ethinylestradiol 35
micrograms)Tablets as specified under this Patient Group Direction

Register of Staff Trained and Assessed to Administer or Supply this Medicine:
(additional sheets may be attached)

“I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct”.

<table>
<thead>
<tr>
<th>Name of authorised practitioner</th>
<th>Signature of authorised practitioner</th>
<th>Clinical manager or GP</th>
<th>Signature of clinical manager or GP</th>
<th>Date</th>
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