NHS Borders

Patient Group Direction for the supply and/or administration of Gedarel 30/150 /Marvelon (Ethinylestradiol 30mcg and Desogestrel 150mcg) to a named individual attending NHS Borders Sexual Health

This document authorises the supply and/or administration of Gedarel 30/150 /Marvelon (Ethinylestradiol 30mcg and Desogestrel 150mcg) by NHS Borders Sexual health Nurses to a named individual who meets the criteria for inclusion under the terms of the document

The NHS Borders Sexual Health Nurse seeking to supply Gedarel 30/150 /Marvelon (Ethinylestradiol 30mcg and Desogestrel 150mcg) 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 Reviewed by: Dr Ailsa Wylie, Gillian Forbes, Liz Leitch, Gavin Gorman

Patient Group Direction for the supply and/or administration of Gedarel 30/150 /Marvelon (Ethinylestradiol 30mcg and Desogestrel 150mcg) for a named individual by a registered nurse who has a Family Planning Certificate, recent Family planning experience, and has undergone training for this Patient Group Direction

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

Name of medicine,	**Gedarel 30/150/Marvelon (Ethinyloestradiol 30mcg and Desogestrel 150mcg)** **(Marvelon only to be used if Gedarel not available)**
Legal status	**Prescription Only Medicine (POM)**
Storage	**Store at Room Temperature**
Dose	First treatment cycle 1 tablet daily for 21 days, starting on the first day of the menstrual cycle. Contraceptive protection begins immediately. For subsequent cycles tablet taking from the next pack of Gedarel/Marvelon is continued after a 7-day interval, beginning on the same day of the week as the first pack.
Route/method	**Oral**
Frequency	One tablet daily for 21 days; subsequent courses repeated after 7 day pill free interval.
Total dose Quantity	One packet containing a maximum of 21 x 3 tablets. Six month supply at subsequent visits. If the woman has used the pills with no problems for 6 months and there are no contraindications, then a 12 month supply can be offered.
Advice to Patients	❖ Explain potential benefits and adverse effects of the Combined Oral Contraceptive, referring to both "minor" and "serious" effects. ❖ Discuss risks e.g. venous thromboembolism especially increased during prolonged travel of more than 5 hours. Gedarel/Marvelon is a 3rd generation pill and has an increased VTE risk of 25 per 100, 000 women compared with 15 per 100, 000 women with Microgynon 30 (which is 2nd generation). ❖ If focal migraine, stop pill immediately. ❖ Diabetics may find that their insulin or oral anti-diabetic dose may need to be altered as an

	effect of the COC on glucose tolerance. ❖ Advise women to contact their nurse/ GP/ Sexual Health Staff if they develop any adverse effects. ❖ Advise on mode of action, how to take, efficacy, advantages and disadvantages. ❖ Discuss 7 day rule, missed pill advice, safer sex. ❖ Provide Family Planning and Manufacturers information sheets. ❖ Provide with contact numbers for telephone help. ❖ Advise to seek advice if any concerns.
Follow up	❖ Advise women to contact their nurse/ GP/ Sexual Health Staff if they develop any adverse effects. ❖ The woman should be reviewed within three months of starting COC or sooner if problems. ❖ If changing from another method advise on appropriate starting regime

2. Clinical condition:

Clinical Condition to be treated	Clients self referring to Family Planning and requesting combined oral contraception. Marvelon is not a first line contraceptive. Please see Borders Joint Formulary.
Criteria for inclusion	Any woman who presents for combined oral contraception with no factors in their medical history that give concern about any increased risk for them with Combined Oral Contraceptive (WHO category I) Starting regimes: a) Please refer to the Faculty of Sexual & Reproductive Health – FSRH CEU Guidance **'Combined Oral Contraception- First Prescription of COC" (Updated 2007.)** for full details on recommended starting routines. b) Starting the COC 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 COC can be discontinued should Levonelle fail and a pregnancy occur. If the COC 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 COC immediately following hormonal emergency contraception (Levonelle) should

	be made on an individual basis and in discussion with the client.
Criteria for exclusion	❖ Age less than 14 years ❖ Age more than 45 years ❖ Smoking and over 35 years ❖ BP over140/90 mmHg ❖ Pregnancy ❖ Less than 21 days postpartum ❖ Breastfeeding ❖ Migraine with aura ❖ BMI greater than 35 ❖ Severe disturbances of liver function, jaundice or persistent itching during a previous pregnancy, Dubin-Johnson syndrome, Rotor syndrome, previous or existing liver tumours. Cirrhosis. ❖ Gall bladder disease ❖ Existing or a history of confirmed venous thromboembolism (VTE), family history of idiopathic VTE, other known risk factors for VTE. ❖ SLE ❖ Immobility ❖ Secondary Raynauds disease with Lupus Anticoagulant ❖ Crohns disease/ Ulcerative Colitis ❖ Current HIV, on HAART ❖ Existing or previous arterial thrombotic or embolic processes. ❖ Conditions which predispose to thromboembolism e.g. disorders of the clotting processes, valvular heart disease and atrial fibrillation, congenital heart disease. ❖ Sickle-cell anaemia. ❖ Breast or endometrial carcinoma, or a history of these conditions. ❖ Trophoblastic disease (Molar pregnancy) where hcg abnormal ❖ Severe diabetes mellitus with vascular changes. ❖ Disorders of lipid metabolism. ❖ History of herpes gestationis. ❖ Deterioration of otosclerosis during pregnancy. ❖ Undiagnosed abnormal vaginal bleeding. ❖ Hypersensitivity to any of the components of Gedarel/Marvelon ❖ Fraser guidelines not met in under 16s.
Action if excluded	Seek telephone advice from doctor. If doctor unavailable consider Progesterone-Only Pill and make arrangements for client-doctor consultation

Action if declines	Document in notes and if required discuss with Doctor
Interactions with other medicaments and other forms of interaction	Hepatic enzyme inducers such as barbiturates, primidone, phenobarbitone, phenytoin, phenylbutazone, rifampicin, carbamazepine and griseofulvin can impair the efficacy of GedarelMarvelon. For women receiving long-term therapy with hepatic enzyme inducers, another method of contraception should be used. Women receiving short courses of enzyme inducers should take additional, non-hormonal (except rhythm or temperature method) contraceptive precautions during the time of concurrent medication and for 7 days afterwards. With rifampicin, additional contraceptive precautions should be continued for 4 weeks after treatment stops, even if only a short course was administered. The requirement for oral antidiabetics or insulin can change as a result of the effect on glucose tolerance. The herbal remedy St John's wort (Hypericum perforatum) should not be taken concomitantly with Marvelon/ Gedarel as this could potentially lead to a loss of contraceptive effect

3. Documentation/Record keeping:-

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

Name and brand of preparation
Batch number and expiry date
Dose given
Route and site of administration
Date
Signature

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

Standards must be consistent with the Summary of Product Characteristics.

4. Professional Responsibility.

- All Health Professionals will ensure he/she has the relevant training and is competent in all aspects of medication, including contra-indications and the recognition and treatment of adverse effects. He/she will attend training updates as appropriate.
- 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/indexasp?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 can be sourced on Faculty Sexual and Reproductive Healthcare website www.fsrh.org
- SPC Gedarel 30/150/Marvelon
  http://www.medicines.org.uk/EMC/medicine/5383/SPC/Marvelon/

Patient Group Direction for provision and/or administration of Gedarel 30/150/Marvelon (ethinylestradiol 30mcg and desogestrel 150mcg) by health professionals employed by NHS Borders

This Patient Group Direction is approved for use by the under-signed :			
Job Title	**Name**	**Signed**	**Date**
Senior Doctor/Dentist for relevant clinical area	Dr Ross Cameron		22/6/11
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 22/6/11
Signed by ADTC CHAIRPERSON: .....
Name: ...John Hammond.....

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

Name of Health Professional	Job Title	Signed	Date