PGD 03CP: Levonorgestrel 1500 microgram for EHC (licensed & unlicensed use)

Issue Date: September 2017

1. Clinical Condition

1.1	Situation/condition	Women requiring Emergency Hormonal Contraception (EHC)
1.2	Criteria for inclusion	Women of childbearing age having had unprotected sexual intercourse or failure of usual contraception method within 72 hours of unprotected sexual intercourse Women presenting within 72 hours of unprotected sexual intercourse who have vomited within 3 hours of taking EHC Women who have received EHC once already in this cycle and subsequently had unprotected sexual intercourse or failure of usual contraception method within 72 hours ***Unlicensed indications:*** *Women taking enzyme-inducing drugs within the last 4 weeks (two tablets per dose)* *Women suffering from severe diarrhoea or severe malabsorption syndromes (two tablets per dose)* *Women weighing > 70kg or with a BMI >26kg/m² (two tablets per dose)*
1.3	Criteria for exclusion	3rd party presentation Last unprotected sexual intercourse (UPSI) more than 72 hours prior to presentation Suspected pregnancy, at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy), lower abdominal pain or unexplained bleeding Known allergy to Levonorgestrel or excipients in the tablet. Contains lactose (galactose intolerance, Lapp lactase deficiency, or glucose – galactose malabsorption) Current severe liver disease including jaundice Acute porphyria (with or without symptoms) Women under 16 & not Fraser competent Use of ulipristal (Ellaone) in current cycle Women who have already received 2 supplies of EHC in current cycle Clients taking ciclosporin (may cause ciclosporin toxicity)
1.4	Action if patient excluded	Discuss with client the reason for exclusion and document on the consultation record form Discuss with client alternative methods of emergency contraception. Refer to clients own GP or local sexual health service
1.5	Cautions	The effectiveness of levonorgestrel is reduced by the concomitant use of enzyme inducing drugs within the last 4 weeks e.g. carbamazepine, efavirenz, eslicarbazepine, griseofulvin, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, rifabutin, rifampicin, St John's Wort and topiramate. Please refer to current SPC and BNF for full details Severe intestinal malabsorption syndromes e.g. Crohn's Disease (may impair efficacy) Women weighing >70kg or with a BMI >26kg/m²

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1.6	Action if patient declines	Document consultation and reason/s client declined, discuss alternative method to be used and/or referral

2. Description of Treatment

2.1	Name of Medicine	Levonorgestrel 1500 micrograms
2.2	Legal status	POM
2.3	Licensed or unlicensed	Licensed (Faculty of Sexual and Reproductive Healthcare (FSRH) best practice guidance supports use in under 16 years and unlicensed indication doses)
2.4	Dose	**Licensed indication** One tablet to be taken as soon as possible, preferably within 12 hours and no later than 72 hours following unprotected sexual intercourse If vomiting occurs within 3 hours of taking the tablet, another 1500mcg tablet can be supplied and should be taken immediately **Unlicensed Indications: enzyme inducing drugs within the last 4 weeks, malabsorption syndrome, or women weighing > 70kg or with a BMI >26kg/m²** Women suffering from severe diarrhoea or severe malabsorption syndromes or who are taking enzyme-inducing drugs within the last 4 weeks should take **two tablets** as soon as possible. This should be documented as such and there should be appropriate discussion with the patient Women should be informed that it is possible that higher weight or BMI could reduce the effectiveness of Levonorgestrel and that two tablets should be taken as soon as possible. This should be documented as such and there should be appropriate discussion with the patient
2.5	Route of Administration	Oral
2.6	Supply	Licensed indication: **One tablet** Unlicensed indications: enzyme inducing drugs within the last 4 weeks or malabsorption syndrome or women weighing >70kg or with BMI >26kg/m²: **Two tablets**
2.7	Side Effects	Generally well tolerated, but side effects may include nausea and vomiting, low abdominal pain, breast tenderness, headache, dizziness, fatigue and temporary disturbance of bleeding patterns Please refer to current SPC or BNF for full details

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2.8	Written/verbal advice	Having established inclusion criteria and excluded contraindications, provide the patient with comprehensive information concerning: How to take the treatment including:- 1. Take immediately or as soon as practical. 2. If vomiting occurs within 3 hours advise obtain a further supply by returning to the clinic or visiting a local pharmacy 3. Advise that the treatment is most effective the sooner it is taken after UPSI or failure of routine method of contraception - a glass of water may be offered to the client so that they may take the medicine on the premises Failure rate of treatment Advise client that an intra-uterine contraceptive device (IUCD) is the most effective form of emergency contraception. If a client wishes to have an IUCD fitted please issue levonorgestrel if not excluded, and refer to GP or Sexual Health Team. Advise to seek medical advice if lower abdominal pain occurs. Advise to perform pregnancy test if menstrual bleeding is delayed by more than 5 days or menstrual bleed is lighter than normal or abnormal bleeding occurs. A 99% accurate pregnancy test can be done 3 weeks after last unprotected sexual intercourse. If an unlicensed indication, inform the client that this is current best practice. A manufacturer's patient information leaflet must be provided to patients who have a medicine supplied under a PGD. Advice must be given regarding on-going contraception including the importance of using a barrier method (e.g. condom, diaphragm or cap) or abstinence for the remainder of the current cycle. Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing at least 8 hours following levonorgestrel administration. The possible risk of exposure to a sexually transmitted infection and details of the level 3 sexual health service should screening be indicated. If not taken on the premises label the pack as per dispensed medicine and provide a patient information leaflet. Counselling will be undertaken verbally and in conjunction with manufacturer's product information leaflets.	**Condition and product specific - MUST be used with the signed PGD Suite**

2.9	Records	A copy of the consultation record must be completed at the time of supply All records must be stored securely for 8 years or until the patient's 25th birthday (whichever is longer). Undertake a Fraser competence assessment for those under 16. Undertake a risk assessment for sexual exploitation for those under 18.	

References

- Faculty of Sexual and Reproductive Healthcare (FSRH) Guidance; Emergency Contraception, last updated March 2017
- BNF Vol 73 March 2017
- Summary Product Characteristics Levonorgestrel, www.medicines.org.uk