NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Shortages of 'low dose estrogen' monophasic 21-day combined oral contraceptives (COC)

Date: 3rd April 2019

Description of products affected

- Combined oral contraception (COC) contains an estrogen paired with a progestogen in different formulations.[1]
- COC is considered low dose if it contains 20mcg of the synthetic estrogen, ethinylestradiol.[1]
- Low strength preparations are particularly appropriate for women with risk factors for circulatory disease, provided a combined oral contraceptive is otherwise suitable.[2]
- Progestogens, the other components of COC are sometimes grouped by 'generation' according to the time they were first marketed as constituents of COCs.[1]
    - First: Norethisterone
    - Second: Levonorgestrel
    - Third: Desogestrel, gestodene, norgestimate*
    - Newer/other: Drospirenone, dienogest, nomegestrol acetate

*Sometimes classified as second generation: levonorgestrel is one of its active metabolites.

Background

There are various formulations of 'low dose estrogen' COC but currently there are supply issues with some of these formulations (see table below).

Table 1 – Availability of formulary choice 'low dose estrogen' COC

Formulation	Availability
20mcg ethinylestradiol and 1mg norethisterone:	
Loestrin 20	No stock and no date when issue will resolve.
20mcg ethinylestradiol and 150mcg desogestrel:	
Gedarel 20/150 **'NEW' Preferred option in primary care.**	Stock available.
Mercilon 20/150	Stock available but more expensive than alternatives.
Munalea 20/150	No stock as this formulation has been discontinued. This was previously 1st line in Primary Care
20mcg ethinylestradiol and 75mcg gestodene:	
Aidulan 20/75	Stock currently available but being discontinued. This was previously 1st line in Primary Care
Millinette 20/75 **'NEW' Preferred option in primary care.**	Stock available.
Sunya 20/75	Stock available but more expensive than alternatives.

Alternative agents and management options

- Preferred option is to maintain the patient on their usual brand of 'low dose estrogen' COC. In the first instance the patient should be encouraged to try several pharmacies in order to fulfil their prescription for their usual brand of 'low dose estrogen' COC. Different pharmacies use a range of wholesalers and distributors. The patient may wish to ring pharmacies in advance of attending to ascertain availability.

- Review patient's contraception to consider if a 'low-dose' estrogen COC is clinically appropriate and consider switching to a monophasic **standard strength** where suitable. **Current formulary choice in primary care for monophasic standard strength 21-day preparation COC is Maexeni 30/150mcg tablets (30mcg ethinylestradiol and 150mcg levonorgestrel).**

- It is important to involve any patients (and their carers as appropriate) in the discussion regarding any planned change to their medication **BEFORE** making the change.

- Where there is a clinical need for a 'low-dose' estrogen COC and the patient's usual brand is unavailable consider switching patient to an alternative brand of 'low dose' estrogen COC as listed above in Table 1.

- Evidence has shown that third generation progestogens i.e. desogestrel or gestodene are associated with a greater risk of VTE (differences not always statistically significant).[1] The alternative 'low-dose' estrogen COC preparations may be unsuitable for women with cardiovascular risk factors and an individual assessment of alternative contraceptive options may be required.

- Women should be advised that use of any COC is associated with an increased risk of VTE, but the absolute risk of VTE for an individual COC user remains very small.[1]

- If the patient's previous contraceptive brand was used correctly or pregnancy can reasonably be excluded, the patient should be counselled to **start the first active tablet of the new brand COC the day after the last active pill of the old brand, without the 7-day hormone (pill) free interval** to maintain contraceptive efficacy. For further information see individual monographs for requirements of specific preparations.[1,2]

- If the woman decides to take the 7-day hormone (pill) free interval before starting the new COC, assess the need for additional contraception i.e. barrier methods for 7 days and emergency contraception.[3]

References

1. The Faculty of Sexual and Reproductive Healthcare Guideline (February 2019) Combined Hormonal Contraception. Available at: https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/fsrh-combined-hormonal-contraception-guideline-february-2019.pdf (Accessed: 21 March 2019)
2. Joint Formulary Committee (2019) British National Formulary. Available at: http://bnf.nice.org.uk (Accessed: 19 February 2019)

3. CKS: Contraception – combined hormonal methods. Available at: https://cks.nice.org.uk/contraception-combined-hormonal-methods#!topicSummary (Accessed: 28 March 2019)
4. SPC for Loestrin 20 tablets accessed via electronic Medicines Compendium. Available at: https://www.medicines.org.uk/EMC/medicine/1425/SPC/Loestrin+20/ (Accessed: 28 March 2019)
5. SPC for Gedarel 20/150mcg tablets accessed via electronic Medicines Compendium. Available at: https://www.medicines.org.uk/emc/product/4217/smpc (Accessed: 28 March 2019)
6. SPC for Mercilon tablets accessed via electronic Medicines Compendium. Available at: https://www.medicines.org.uk/emc/product/1360 (Accessed: 28 March 2019)
7. SPC for Munalea 20/150mcg tablets accessed via electronic Medicines Compendium. Available at: https://www.medicines.org.uk/emc/product/5077/smpc (Accessed: 28 March 2019)
8. SPC for Aidulan 20/75mcg tablets accessed via electronic Medicines Compendium. Available at: https://www.medicines.org.uk/emc/product/5079/smpc (Accessed: 28 March 2019)

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