Estradiol Valerate and Dienogest (Qlaira®) for Oral Contraception

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of Estradiol Valerate and Dienogest (Qlaira®) for use solely as an oral contraceptive.

Qlaira is also licensed for the treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraception – see separate GREEN Pan Mersey statement for this indication


Qlaira is a quadriphasic combined oral contraceptive (COC) that is given by continuous daily administration. It contains the oestrogen estradiol valerate, and the progestogen Dienogest. Its contraceptive efficacy appears to be similar to that reported for other COCs. Clinical trials data suggest that side effects and tolerability are also comparable to those of other COCs.

The Pan Mersey Area Prescribing Committee does not recommend Qlaira as a COC because:

- The Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit considers Qlaira to be no more effective than other combined pills, with similar cycle control to a low dose COC.
- There is a lack of long term safety data.
- It is five times as expensive as the average existing COC cost.

Alternative treatments are other standard Combined Oral Contraceptives.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.
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### EFFECTIVENESS

No advantages have been demonstrated for Qlaira over standard COCs in terms of efficacy or unwanted effects.\(^1\),\(^2\)

Only one comparator trial has been fully published. The primary efficacy outcomes were bleeding pattern and cycle control, not contraceptive efficacy.\(^3\) Also, the comparator COC in the trial did not contain the recommended starting dose of oestrogen. Although pregnancy was not a primary outcome, the trial report stated that one unintended pregnancy occurred in the Qlaira group, and was attributable to “method failure”.\(^1\)

The Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit states that clinical trials suggest that Qlaira is as effective as other combined pills and has similar cycle control to a low dose COC.\(^4\)

### SAFETY

No epidemiological data have been reported on the effects of COCs containing estradiol or estradiol valerate. All the warnings and precautions are derived from clinical and epidemiological data of ethinyl estradiol containing COCs.\(^1\) Currently the risks and benefits of taking Qlaira have to be assumed to be the same as for other COCs.\(^4\)

The contraindications, warnings, cautions and side effects listed in the Summary of Product Characteristics (SPC) are similar to COCs.

If any of the conditions/risk factors specified in the SPC are present, the benefits of Qlaira should be weighed against the possible risks for each individual woman.\(^5\),\(^6\)

See [SPC](http://www.medicines.org.uk/emc/medicine/21700/SPC/Qlaira) for full details.

### COST\(^7\)

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<tr>
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<th>Cost (£)</th>
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<tr>
<td>Qlaira</td>
<td>100.72/year</td>
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<tr>
<td>Other COCs average</td>
<td>22.56/year</td>
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### PATIENT FACTORS

Qlaira has a quadriphasic dosage regime.

Standard guidance on missed pills cannot be applied to Qlaira and the manufacturer’s advice is complex.\(^1\),\(^2\),\(^5\)

### IMPLEMENTATION NOTES

Qlaira is not recommended for use solely as a Combined Oral Contraceptive.

### REFERENCES

4. Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. The estradiol valerate/dienogest combined pill, Qlaira®. September 2009.
6. Venous Thromboembolism (VTE) and Hormonal Contraception; Faculty of Sexual and Reproductive Healthcare statement;11/2014