Qlaira®, film-coated tablets (estradiol valerate/dienogest) Prescribing Information (Refer to full Summary of Product Characteristics (SmPC) before prescribing) **Presentation:** Each wallet (28 film-coated tablets) contains in the following order: 2 dark yellow tablets each containing 3 mg estradiol valerate, 5 medium red tablets each containing 2 mg estradiol valerate & 2 mg dienogest, 17 light yellow tablets each containing 2 mg estradiol valerate & 3 mg dienogest, 2 dark red tablets each containing 1 mg estradiol valerate, 2 white placebo tablets **Indication(s):** Oral contraception. Treatment of heavy menstrual bleeding in women without organic pathology who desire oral contraception. The decision to prescribe Qlaira should consider the individual woman's current risk factors, particularly those for venous thromboembolism (VTE) & how the risk of VTE with Qlaira compares with other combined hormonal contraceptives (CHCs). **Posology & method of administration:** One tablet daily for 28 consecutive days, starting on the first day of the menses. Each subsequent pack is started the day after the last tablet of the previous wallet. Incorrect use, GI upset or concomitant medication may necessitate additional barrier contraception. Prescribers should consult the SmPC. ***Children & adolescents:*** No data available for use in adolescents (<18 years). ***Geriatric patient:*** Qlaira is not indicated after menopause. ***Hepatic impairment:*** Contraindicated in women with severe hepatic diseases. ***Renal impairment:*** No specific studies. **Contraindications:** Do not use in the following conditions & stop use immediately if any appear for the first time during use - Presence or risk of VTE: current VTE or history of DVT or PE, known hereditary or acquired predisposition for VTE, major surgery with prolonged immobilisation, a high risk of VTE due to the presence of multiple risk factors. Presence or risk of arterial thromboembolism (ATE): current or history of ATE or prodromal condition, cerebrovascular disease – current stroke, history of stroke or prodromal condition, known hereditary or acquired predisposition for ATE, such as hyperhomocysteinaemia and antiphospholipid-antibodies, history of migraine with focal neurological symptoms, a high risk of ATE due to multiple risk factors or to the presence of one serious risk factor such as diabetes mellitus with vascular symptoms, severe hypertension or severe dyslipoproteinaemia; severe hepatic disease if liver tests not returned to normal; previous or existing liver tumours; suspected or existing hormone-dependent malignancies; undiagnosed vaginal bleeding; hypersensitivity to components **Warnings & precautions:** Prior to initiation/reinstitution of Qlaira exclude pregnancy & evaluate risk of thrombosis. Ensure woman's awareness of information on VTE & ATE, including risk of Qlaira compared with other CHCs, symptoms of VTE & ATE, known risk factors & what to do in the event of a suspected thrombosis. In cases of suspected or confirmed VTE or ATE, discontinue Qlaira & use alternative contraception if anticoagulants are initiated because of teratogenicity of anticoagulant therapy (coumarins). In the presence of the following conditions or risk factors, or in the event of aggravation, or first appearance of any of these conditions, the suitability of Qlaira use should be discussed with the woman or discontinuation considered. The following warnings & precautions are mainly derived from clinical & epidemiological data of ethinylestradiol-containing CHCs. Risk of VTE: Use of any CHC increases risk of VTE compared with no use. Products that contain levonorgestrel, norgestimitate or norethisterone are associated with the lowest risk of VTE. Limited data suggests that Qlaira may have a risk of VTE in the same range. The decision to use any other product (such as Qlaira) than one known to have the lowest VTE risk should be taken only after a discussion with the woman to ensure she understands the risk of VTE with CHCs, how her current risk factors influence this risk & that her VTE risk is highest in the first ever year of use. There is also some evidence that the risk is increased when a CHC is re-started after a break in use of 4 weeks or more. VTE may be fatal in 1-2% of cases. Extremely rarely, thrombosis has been reported to occur in CHC users in other blood vessels, e.g. hepatic, mesenteric, renal or retinal veins & arteries. Risk for VTE complications in CHC users may increase substantially in a woman with additional risk factors, particularly if there are multiple risk factors. Qlaira is contraindicated if a woman has multiple risk factors that put her at high risk of venous thrombosis. Risk for ATE: Epidemiological studies have associated the use of CHCs with an increased risk for ATE. ATE events may be fatal. Risk of ATE complications or of a cerebrovascular accident in CHC users increases in women with risk factors. Qlaira is contraindicated if a woman has one serious or multiple risk factors for ATE that puts her at high risk of arterial thrombosis. The total risk of VTE or ATE should be considered as increase in risk may be greater than sum of individual risk factors. If benefit/risk balance is negative a CHC should not be prescribed. For a list of VTE or ATE risk factors & symptoms consult the SmPC. Some studies suggest increased risk of cervical & breast cancer. Hepatic tumours have been reported with isolated cases of life-threatening intra-abdominal haemorrhages. Possible increase in risk of pancreatitis if presence or family history of hypertriglyceridaemia. Following conditions may occur or deteriorate: jaundice/pruritus related to cholestasis, gallstones, porphyria, SLE, HUS, Sydenham's chorea, herpes gestationis, otosclerosis-related hearing loss, depression, epilepsy, Crohn's disease, ulcerative colitis. Advise women to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating treatment. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Stop CHC use if disturbances in liver function occur, until the markers return to normal. Stop CHC use if recurrence of sex steroid related cholestatic jaundice occurs. Hereditary angioedema may be induced or exacerbated. No requirement to alter regimen in diabetics but monitor carefully. Chloasma may occur - if tendency, advise avoidance of sun/UV radiation. Qlaira contains lactose. Advise that hormonal contraceptives do not protect against HIV infections & other STDs. Investigate bleeding irregularities that occur after regular cycles & exclude malignancy or pregnancy. **Interactions:** Interaction with specific drugs may necessitate additional barrier contraception. Qlaira may affect the metabolism of other medicines. Lab tests may be affected. **Pregnancy & lactation:** Do not use. If pregnancy occurs, stop usage immediately. The increased risk of VTE during the postpartum period should be considered when re-starting Qlaira. **Undesirable effects:** *Common:* Headache, abdominal pain, nausea, acne, amenorrhoea, breast discomfort, dysmenorrhoea, intracyclic bleeding, weight increased. *Serious: cf. CI/W&P – in addition:* VTE, ATE, hypertension, myocardial infarction, cervical dysplasia, migraine, uterine leiomyoma, genital haemorrhage, presumed occular histoplasmosis syndrome, ruptured ovarian cyst, depression, mental disorders, focal nodular hyperplasia of the liver, chronic cholecystitis. Erythema nodosum, erythema multiforme, breast discharge & hypersensitivity have occurred under treatment with ethinylestradiol-containing COCs. Prescribers should consult the SmPC in relation to other side effects. **Overdose:** No reports of serious deleterious effects from overdose. Possible symptoms: nausea, vomiting & slight vaginal bleeding in young girls. No antidotes - treatment should be symptomatic. **Legal Category:** POM **Package Quantities & Basic NHS Costs:** £25.18 per 3 x 28 tablets **MA Number(s):** PL 00010/0576 **Further information available from:** Bayer plc, 400 South Oak Way, Green Park, Reading, RG2 6AD, United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** June 2024

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Adverse events should be reported.
Reporting forms and information can be found at
https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Bayer Plc. Tel.: 0118 206 3500,
Email: pvuk@bayer.com