QLAIRA® - Estradiol valerate / Dienogest film coated tablets. Composition: 26 hormone-containing film-coated tablets in the following order: 2 dark yellow tablets each containing 3mg estradiol valerate EP; 5 medium red tablets each containing 2mg estradiol valerate EP and 2mg Dienogest IP; 17 light yellow tablets each containing 2mg estradiol valerate EP and 3mg Dienogest IP. 2 dark red tablets each containing 1mg estradiol valerate EP; 2 hormone-free white film-coated tablets. Excipient: lactose (no more than 50 mg per tablet) Indication: Heavy Menstrual Bleeding: Qlaira is indicated for the treatment of heavy menstrual bleeding in women without organic pathology who choose to use an oral contraceptive as their method of contraception. Posology and method of administration: Oral use. Dosage regimen How to take Qlaira Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. Tablet taking is continuous. One tablet is to be taken daily for 28 consecutive days. Each subsequent pack is started the day after the last tablet of the previous calendar pack. Withdrawal bleeding usually starts during the intake of the last tablets of a calendar pack and may not have finished before the next calendar pack is started. In some women, the bleeding starts after the first tablets of the new calendar pack are taken. How to start Qlaira: No preceding hormonal contraceptive use (in the past month) Tablet-taking has to start on day 1 of the woman's natural cycle (i.e., the first day of her menstrual bleeding). Changing from a combined hormonal contraceptive (combined oral contraceptive/COC), vaginal ring, or transdermal patch. The woman should start with Qlaira on the day after the last hormone-containing tablet of her previous COC. In case a vaginal ring or transdermal patch has been used, the woman should start using Qlaira on the day of removal of the last ring or patch of a cycle pack. Changing from a progestogen-only method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS) The woman may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to additionally use a barrier method for the first 9 days of tablet- taking. Following first-trimester abortion The woman may start immediately. When doing so, she does not need additional contraceptive measures. Following delivery or second-trimester abortion. Use in Special populations – Pregnancy & Lactation: Women should be advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, the woman should be advised to additionally use a barrier method for the first 9 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of COC use, or the woman has to wait for her first menstrual period. Contraindications: Combined oral contraceptives (COCs) should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first-time during COC use, the product should be stopped immediately. Presence or a history of venous or arterial thrombotic/ thromboembolic events (e.g., deep venous thrombosis, pulmonary embolism, myocardial infarction) or of a cerebrovascular accident. Presence or history of prodromi of a thrombosis (e.g., transient ischemic attack, angina pectoris). A high risk of venous or arterial thrombosis. History of migraine with focal neurological symptoms. Diabetes mellitus with vascular involvement. Severe hepatic disease as long as liver function values have not returned to normal. Presence or history of liver tumors (benign or malignant). Known or suspected sex-steroid influenced malignancies (e.g., of the genital organs or the breasts). Undiagnosed vaginal bleeding. Known or suspected pregnancy. Hypersensitivity to the active substances or to any of the excipients. Special warnings and special precautions for use: If any of the conditions/risk factors mentioned below is present, the benefits of COC use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start using it. In the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors, the woman should contact her physician. The physician should then decide on whether COC use should be discontinued. The following warnings and precautions are mainly derived from clinical and epidemiological data of ethinylestradiol containing COCs. Circulatory disorders: Arterial and Venous Thrombotic and Thromboembolic disorders such as myocardial infarction, deep venous thrombosis, pulmonary embolism and of cerebrovascular accidents; Tumors: Cervical, Breast and Benign and Malignant Liver Conditions (rare); Others: Hypertriglyceridemia, Hypertension. Drug Interactions: Effects of other medicinal products on Qlaira Interactions can occur with drugs that induce microsomal enzymes which can result in increased clearance of sex hormones, and which may lead to breakthrough bleeding and/or contraceptive failure. Women on treatment with any of these drugs should temporarily use a barrier method in addition to the COC or choose another method of contraception. The barrier method should be used

during the time of concomitant drug administration and for 28 days after their discontinuation. Substances increasing the clearance of COCs (diminished efficacy of COCs by enzyme- induction), e.g.: Phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin and products containing St. John's wort. The effect of the CYP 3A4 inducer rifampicin was studied in healthy postmenopausal women. Co-administration of rifampicin with Estradiol valerate/Dienogest tablets led to significant decreases in steady state concentrations and systemic exposures of Dienogest and estradiol. The systemic exposure of Dienogest and Estradiol at steady state, measured by AUC(0-24h), were decreased by 83% and 44%, respectively. Substances with variable effects on the clearance of COCs, e.g.: When co-administered with COCs, many HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors can increase or decrease plasma concentrations of estrogen or progestin. These changes may be clinically relevant in some cases. Substances decreasing the clearance of COCs (enzyme inhibitors) Dienogest is a substrate of cytochrome P450 (CYP) 3A4 Strong and moderate CYP3A4 inhibitors such as azole antifungals (e.g., itraconazole, voriconazole, fluconazole), verapamil, macrolides (e.g., clarithromycin, erythromycin), diltiazem and grapefruit juice. can increase plasma concentrations of the estrogen or the progestin or both. In a study investigating the effect of CYP3A4 inhibitors (ketoconazole, erythromycin), steady state Dienogest and Estradiol plasma levels were increased. Co-administration with the strong inhibitor ketoconazole resulted in a 2.86-fold increase of AUC (0-24h) at steady state for Dienogest and a 1.57-fold increase for estradiol. When co-administered with the moderate inhibitor erythromycin, the AUC (0-24h) of Dienogest and estradiol at steady state were increased by 1.62-fold and 1.33-fold, respectively. Effects of Qlaira on other medicinal products Oral contraceptives may affect the metabolism of certain other drugs. Accordingly, plasma and tissue concentrations may either increase or decrease (e.g., lamotrigine). However, based on the in vitro data, inhibition of CYP enzymes by Qlaira is unlikely at the therapeutic dose. Use in special populations: Pregnancy Qlaira is not indicated during pregnancy. If pregnancy occurs during use of Qlaira, further intake must be stopped. However, extensive epidemiological studies with EE-containing COCs have revealed neither an increased risk of birth defects in children born to women who used COCs prior to pregnancy, nor a teratogenic effect when COCs were taken inadvertently during early pregnancy. Lactation: Lactation may be influenced by COCs as they may reduce the quantity and change the composition of breast milk. Therefore, the use of COCs should generally not be recommended until the nursing mother has completely weaned her child. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk. Children and adolescents Qlaira is only indicated after menarche. Geriatric patients. Not applicable. Qlaira is not indicated after menopause. Patients with hepatic impairment Qlaira is contraindicated in women with severe hepatic diseases. Patients with renal impairment Qlaira has not been specifically studied in renally impaired patients. Available data do not suggest a change in treatment in this patient population. Undesirable effects: Summary of the safety profile the most commonly reported adverse reactions with Qlaira when used in the treatment of heavy and/or prolonged menstrual bleeding in women without organic pathology who elect to use oral contraception are nausea, breast pain, and unscheduled uterine bleeding. They occur in > 2 % of users. Serious adverse reactions are arterial and venous thromboembolism. Description of selected adverse reactions Adverse reactions with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives are listed below: Tumors The frequency of diagnosis of breast cancer is very slightly increased among OC users. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. Causation with COC use is unknown. Liver tumors (benign and malignant). Other conditions Erythema nodosum, Erythema multiforme, Breast discharge, Women with hypertriglyceridemia (increased risk of pancreatitis when using COCs), Hypertension, Occurrence or deterioration of conditions for which association with COC use is not conclusive: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; hemolytic uremic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; In women with hereditary angioedema exogenous estrogens ; may induce or exacerbate symptoms of angioedema; Liver function disturbances; Changes in glucose tolerance or effect on peripheral insulin resistance; Crohn's disease, ulcerative colitis; Chloasma; Hypersensitivity (including symptoms such as rash, urticaria) Overdose: There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in case of taking an overdose of

hormone-containing film-coated tablets are nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and further treatment should be symptomatic. Storage and handling information: Keep out of the reach and sight of children. Store at room temperature. For further prescribing information, please contact Bayer Zydus Pharma Private Limited, Central Avenue, Bayer House, Hiranandani Estate, Thane - 400607. Source: Version No. QL_2023_01 dated 17 Jul 2023. Reference: Based on CCDS/CCPI Version 11 dated 12 Dec 2018 & US PI dated Mar 2012

Any kind of adverse events should be reported at: drugsafety.mumbai@bayer.com. Please refer to full prescribing information for more information. For the use of healthcare professionals only.