ELOINE® 0.02 mg/3 mg film-coated tablets (ethinylestradiol/ drospirenone) Prescribing Information
(Refer to full Summary of Product Characteristics (SmPC) before prescribing)

Presentation: 24 pink tablets containing 0.020mg ethinylestradiol (as betadex clathrate) & 3mg drospirenone plus 4 white placebo tablets. **Indication:** Oral contraception. The decision to prescribe ELOINE should consider the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), & how the risk of VTE with ELOINE compares with other combined hormonal contraceptives (CHCs). **Posology and method of administration:** One tablet daily for 28 consecutive days. If changing from another contraceptive method, consult the SmPC. Incorrect use, GI upset or concomitant medication may necessitate additional barrier contraception. Prescribers should consult SmPC. **Contra-indications:** 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): 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 function values have not returned to normal; severe renal insufficiency/acute renal failure; presence or history of liver tumours (benign or malignant); known or suspected sex-steroid influenced malignancies; undiagnosed vaginal bleeding; hypersensitivity to the active substances or any excipients. ELOINE is contraindicated for concomitant use with the medicinal products containing ombitasvir/ paritaprevir/ritonavir and dasabuvir, medicinal products containing glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir. Prescribers should consult SmPC. **Warnings:** In cases of suspected or confirmed VTE or ATE discontinue ELOINE & use alternative contraception if anticoagulants are initiated because of the 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 ELOINE use should be discussed with the woman or discontinuation considered. Risk of VTE: use of any CHC increases risk of VTE compared to no use. Products that contain levonorgestrel, norgestimate or norethisterone are associated with the lowest risk of VTE. Other products such as ELOINE may have up to twice this level of risk. Decision to use any product other than one with the lowest VTE risk should be taken only after a discussion with the woman to ensure she understands the risk of VTE with ELOINE, 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. ELOINE is contraindicated if a woman has multiple risk factors that put her at high risk of venous thrombosis. The total risk of VTE should be considered as increase in risk may be greater than sum of individual factors. If benefit/risk balance is negative a CHC should not be prescribed. For a list of VTE risk factors and symptoms consult the full SmPC. Risk for ATE: epidemiological studies have associated use of CHCs with an increased risk for ATE. ATE events may be fatal. Risk of ATE complications or a cerebrovascular accident in CHC users increases in women with risk factors. ELOINE 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 ATE should be considered as increase in risk may be greater than sum of individual factors. If benefit/risk is negative a CHC should not be prescribed. For a list of ATE risk factors and symptoms consult the full SmPC. Some studies suggest increased risk of cervical & breast cancer. Hepatic tumours have been reported with isolated cases of life-threatening intra-abdominal haemorrhages. If concomitant potassium sparing drugs used long-term or pre-treatment serum potassium in upper reference range, test potassium levels in first treatment cycle & continue to monitor in renally impaired patients. Possible increase in risk of pancreatitis if presence or family history of hypertriglyceridaemia. In pre-existing hypertension, constantly elevated or significant increase in blood pressure not responding adequately to antihypertensive treatment, CHC must be withdrawn. 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. Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. 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. If tendency to chloasma present advise avoidance of sun/UV. No requirement to alter regimen in diabetics, but monitor carefully. ELOINE contains lactose. **Precautions:** Prior to inititation/reinstitution of ELOINE exclude pregnancy & evaluate risk of thrombosis. Ensure woman's awareness of information on VTE & ATE, including risk of ELOINE compared with other CHCs, symptoms of VTE and ATE, known risk factors & what to do in event of a suspected thrombosis. 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:** Interactions can occur with drugs that induce microsomal enzymes which can result in increased clearance of sex hormones & may lead to breakthrough bleeding and/or contraceptive failure.When co-administered with CHCs many combinations of HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors can increase or decrease plasma concentrations of oestrogen or progestins. The net effect of these changes may be clinically relevant in some cases.Consult the SmPC for concomitant use. **Pregnancy and lactation:** Do not use. If pregnancy occurs, stop use immediately. The increased risk of VTE in pregnancy and during the postpartum period should be considered when re-starting ELOINE. **Undesirable effects**: Common: emotional lability, headache, nausea, breast pain, irregular bleeding, amenorrhea. Serious: cf. CI/Warnings and Precautions – in addition: VTE, ATE, gastritis, candidiasis anaemia, thrombocythemia, hypersensitivity/ allergic reactions, endocrine disorders, conjunctivitis, tachycardia, hypertension, syncope, hiatus hernia, cholecystitis, erythema nodosum, erythema multiforme, uterine/vaginal bleeding, breast neoplasm, ovarian cyst & oedema, anorexia, alopecia and cervical polyp. Prescribers should consult the SmPC in relation to other side effects. Overdose: Possible symptoms may be nausea, vomiting, slight vaginal bleeding (young girls). No antidotes - treatment should be symptomatic. **Legal Category:** POM. **Package Quantities and Basic NHS Costs:** 3 x 28 tablets £14.70. **MA Number(s):** PL 00010/0575. **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD United Kingdom. Telephone: 0118 206 3000. **Date of preparation:** January 2024.

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 Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel.: 0118 206 3500, Fax.: 0118 206 3703, Email: pvuk@bayer.com

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