Angeliq 1 mg/2 mg film-coated tablets.
Refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Each film coated tablet contains 1 mg oestradiol hemihydrate and 2 mg drospirenone. **Indications:** Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in postmenopausal women more than 1 year post menopause. Prevention of osteoporosis in postmenopausal women at high risk of future fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis. **Posology & method of administration**: One tablet taken daily, whole with some liquid, irrespective of food, preferably at the same time. Each blister is for 28 treatment days, continuously without a break. Women who do not take hormone replacement therapy (HRT) or women who change from another continuous combined product may start treatment at any time. Women changing from a cyclic, sequential combined HRT regimen, treatment should begin the day following completion of the prior regimen. *Special populations*: *Hepatic impairment:* Close supervision is needed. Discontinue treatment with liver function marker deterioration. **Contraindications:** Undiagnosed genital bleeding; known, past or suspected cancer of the breast, oestrogen-dependent malignant tumours (e.g. endometrial cancer); untreated endometrial hyperplasia, previous or current venous thromboembolism (VTE; deep venous thrombosis (DVT), pulmonary embolism (PE); active or recent arterial thromboembolic (ATE) disease; acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal; known thrombophilic disorders; severe renal insufficiency or acute renal failure; hypersensitivity to the active substances or to any of the excipients; porphyria. **Warnings and precautions:** Only initiate if symptoms adversely impact quality of life. Review at least annually and only continue if the benefits outweigh the risks. Evidence regarding the risks of HRT in treating premature menopause is limited. The balance of benefits and risks in younger women may be more favourable than older women. *Conditions needing supervision*: Closely supervise patients if any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment. These conditions may recur or be aggravated during treatment, in particular: leiomyoma (uterine fibroids) or endometriosis; risk factors for thromboembolic disorders; risk factors for oestrogen dependent tumours, e.g. 1st degree heredity for breast cancer; hypertension; liver disorders (e.g. liver adenoma); diabetes mellitus with or without vascular involvement; cholelithiasis; migraine or (severe) headache; systemic lupus erythematosus; a history of endometrial hyperplasia; epilepsy; asthma; otosclerosis. *Reasons for immediate withdrawal of therapy:* Discontinue therapy in case a contra-indication and in the following situations: jaundice or deterioration in liver function; significant increase in blood pressure; new onset of migraine-type headache; pregnancy. *Endometrial hyperplasia and carcinoma:* Breakthrough bleeding or spotting may appear during the first few months. If it appears after some time on therapy, or continues after treatment has been discontinued, investigate the reason. *Breast cancer:* Overall evidence shows an increased risk of breast cancer in women taking combined oestrogen-progestogen or oestrogen-only HRT, that is treatment duration dependent. *Ovarian Cancer:* Use of oestrogen-only or combined oestrogen-progestagen HRT has been associated with a slightly increased risk, within 5 years of use, diminishing over time after stopping. *VTE:* HRT is associated with an increased risk of developing VTE, i.e DVT or PE. An event is more likely in the first year of HRT. Risk factors include oestrogen use, older age, major surgery, personal history or family history obesity, pregnancy/postpartum period, systemic lupus erythematosus and cancer. Discontinue if VTE develops after initiating therapy. Patients should contact their doctors immediately if potential thromboembolic symptoms occur (e.g. painful swelling of a leg, sudden pain in the chest, dyspnoea). *Coronary artery disease:* Slightly increased risk during use of combined oestrogen-progestogen HRT. *Ischaemic stroke:* Oestrogen-only and oestrogen-progestogen therapy is associated with up to 1.5-fold increased relative risk of ischaemic stroke, independent of age or duration of use. *Hepatitis C:* Caution is warranted when co-administering with some anti-viral regimens. *Oestrogens:* May cause fluid retention, monitor renal and cardiac dysfunction patients. *Increases in plasma triglycerides:* Closely follow women with pre-existing hypertriglyceridemia. *Increased thyroid binding globulin levels:* Increases in circulating thyroid hormone, T4 or T3 levels. *HRT does not improve cognitive function*. *Monitor potassium in renal insufficiency. Chloasma may occur:* Especially with a history of cholasma gravidarum. *Each tablet contains 46 mg lactose:* Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions with other medicinal products and other forms of interactions**: *Substances which may increase sex hormone clearance:* Concomitant use of substances inducing drug-metabolising enzymes, specifically cytochrome P450 enzymes, such as anticonvulsants and anti-infectives and possibly also felbamate, griseofulvin, oxcarbazepine, topiramate and products containing the herbal remedy St. John's Wort. Increased metabolism of oestrogens and progestogens may lead to decreased effects and changes in uterine bleeding profile. *Substances with variable effects on sex hormone clearance:* Consult the SmPCs of concomitant HIV/HCV medications. *Substances decreasing sex hormone clearance:* Strong and moderate CYP3A4 inhibitors such as azole antifungals, verapamil, macrolides, diltiazem and grapefruit juice can increase plasma concentrations of the progestin or the oestrogen or both. *Hypertensive women may experience additional blood pressure decreases with concomitant Angeliq and antihypertensive treatment. Concomitant use of Angeliq, NSAIDs and ACE inhibitors / angiotensin II receptor antagonists: Small increases in serum potassium may occur, which is more pronounced in diabetic women. Co-administration of hormone contraceptives containing oestrogens with lamotrigine: Reductions in seizure control may occur* **Pregnancy:** Not indicated during pregnancy. Discontinue promptly if pregnancy occurs. **Breastfeeding:** Not indicated during lactation. **Undesirable effects**: *Common side effects*: Depression, emotional lability, nervousness, headache, abdominal pain, nausea, enlarged abdomen, benign breast neoplasm, breast enlargement, uterine fibroids enlarged, benign neoplasm of cervix uteri, menstrual disorder, vaginal discharge, asthenia, localised oedema. *Additional information on special populations (at least possibly related to Angeliq):* hyperkalaemia, cardiac failure, atrial flutter, QT interval prolonged, cardiomegaly, blood aldosterone increased. Prescribers should consult the SmPC for information on other side effects. **Overdose:** May cause nausea and vomiting and withdrawal bleeding. No antidotes. Treatment should be symptomatic. **Legal category:** POM. **Package Quantities and Basic NHS Costs:** £31.90 per 3 x 28 tablets **Marketing Authorisation Number**: PL 00010/0757. **Further information available from:** Bayer plc, 400 South Oak Way, Reading, RG2 6AD Telephone: 0118 206 3000. **Date of preparation:** August 2025**.**

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Reporting adverse events and quality complaints

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.

If you want to report an adverse event or quality complaint, reports can be directed to Bayer Plc Tel.: 0118 206 3500, Email: **pvuk@bayer.com**

Further information is available on the “contact” tab at www.bayer.co.uk.