Yacella® (0.03mg ethinylestradiol and 3mg drospirenone) (Please refer to the full SmPc before prescribing).

Indication: Oral contraception. The decision to prescribe should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE compares with other combined hormonal contraceptives (CHCs). **Dosage & Administration:** One tablet daily, at about the same time, for 21 consecutive days, starting on Day 1 of the normal menstrual cycle. Start each subsequent pack after a 7-day tablet-free interval, when a withdrawal bleed will occur usually on the 2nd or 3rd day but may not have finished before the next pack is started. Please refer to the SmPC for full advice on starting Yacella, switching from a different contraceptive method, and management of missed tablets or gastrointestinal disturbances (including vomiting and diarrhoea). **Contraindications:** Presence, history or patients at risk of (including hereditary and known predisposition for): cerebrovascular accident (e.g., transient ischaemic attack), venous thrombosis (VTE), arterial thrombosis (ATE, including myocardial infarction) or prodromal conditions (e.g., angina pectoris). High risk of VTE or ATE due to multiple risk factors, or the presence of serious risk factors including: diabetes mellitus with vascular symptoms, severe hypertension and severe dyslipoproteinaemia. Major surgery with prolonged immobilization. History of migraine with focal neurology. Presence or history of liver tumours or severe hepatic disease (with currently abnormal liver function tests). Severe renal insufficiency or acute renal failure. Known or suspected sex-steroid influenced malignancies. Undiagnosed vaginal bleeding. Hypersensitivity to active substance or excipients of the tablet. Rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. Concomitant ombitasvir/paritaprevir/ritonavir/dasabuvir or medicinal products containing glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir. **Precautions & Warnings:** Take a complete history, conduct a physical examination and rule out pregnancy prior to starting or resuming CHC use. Weigh benefits of CHC use against possible risks and discuss with the patient before use. Instruct patients to read the user leaflet carefully and adhere to advice; draw attention to the information on VTE and ATE, and ensure the woman understands the risk of Yacella compared with other CHCs containing levonorgestrel, norgestimate or norethisterone. Include full discussion of individual risk factors, (how risks are highest during the first ever year of use or following a pill-free interval of at least a month), known risk factors and the symptoms of VTE and ATE, and advise what to do in the event of a suspected thrombosis or first appearance of risk factors. If multiple risk factors for ATE and/or VTE are present they may constitute a contraindication; total risk should be considered before prescribing. Increased risk of thromboembolism during puerperium must be considered. Discontinue if thrombosis is suspected or confirmed. Advise women not to smoke if they wish to use a CHC; smokers >35 years of age should be strongly advised to use a different method of contraception. Patients who develop an increase in frequency or severity of migraine should discontinue use and seek medical advice. Please consult SmPC for full information and risk factors for VTE and ATE. Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment. A possible increased risk of cervical cancer has been reported with long-term CHC use. Slightly increased risk of breast cancer has been reported in CHC users, though no direct causation has been shown. This may be due to an earlier diagnosis, biological effects of the pill or a combination of both. In rare cases, hepatic tumours have been reported in users of oral contraceptives. Risk of endometrial and ovarian cancer is reduced with 0.05mg ethinylestradiol, whether this applies to lower-dosed CHC (including Yacella) remains unconfirmed. Check serum potassium during first treatment cycle in patients with renal insufficiency and pre-treatment serum potassium in the upper treatment range, particularly during concomitant use of potassium sparing medicinal products. Women with hypertriglyceridaemia, or family history thereof, may be at an increased risk of pancreatitis when using CHCs. Discontinue if clinically relevant increases in blood pressure occur or in the case of preexisting hypertension with either constantly elevated blood pressure or inadequate response to antihypertensives. Exogenous estrogen may induce or exacerbate symptoms of angioedema. Acute or chronic disturbances of liver function may necessitate discontinuation until liver function returns to normal. Discontinue if cholestatic jaundice/cholestatis-related pruritus previously experienced during pregnancy or sex steroid use recurs. Monitor patients with diabetes during the first months of use. Worsening of endogenous depression, epilepsy, Crohn's disease and ulcerative colitis have been reported during CHC use. Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking CHCs. If anticoagulant therapy is started, adequate alternative contraception should be initiated due to teratogenicity of anticoagulant therapy. As with all CHCs irregular bleeding may occur, especially during the first months of use; evaluate bleeding after approximately three cycles. If bleeding irregularities occur after three months or previously regular cycles, further diagnostic procedures should be considered. Please refer to the SmPC for information on other conditions reported with CHC usage. Patients should be advised to contact their physician in the event of aggravation, exacerbation or first appearance of any of the aforementioned conditions so discontinuation can be considered. Women should be advised that hormonal contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases. Patients on a lactose-free diet should not take Yacella. **Interactions:** Consult prescribing information of concomitant medications for potential interactions. Certain medications may lead to contraceptive failure and/or breakthrough bleeding. Drugs that induce hepatic microsomal enzymes may increase clearance of sex hormones (enzyme induction can be observed after a few days of treatment) and CHCs (diminished efficacy by enzyme-induction), including: barbiturates, phenytoin, carbamazepine**,** rifampicin, bosentan, primidone, HIV medication (ritonavir, nevirapine and efavirenz) and possibly medicines containing Hypericum perforatum (St. John's Wort), oxcarbazepine, topiramate, felbamate and griseofulvin. HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors (including HCV inhibitors) have variable effects on CHC clearance during co-administration, therefore consult prescribing information for HIV/HCV medications prior to concomitant use; in case of any doubt additional barrier contraceptive methods should be used. Concomitant administration of strong CYP3A4 inhibitors can increase plasma concentrations of estrogen and/or progestin. Concomitant etoricoxib may increase plasma concentrations of CHCs containing ethinylestradiol. Women on short-term treatment with medications known to have potential interactions with CHCs should use a barrier method during concomitant use and for 28 days following discontinuation. An alternative reliable and non-hormonal method of contraception is recommended for women on long-term treatment with hepatic enzyme-inducing active substances. If concomitant medicinal product administration runs beyond the end of the tablets in the CHC blister pack, the next pack should be started without the usual tablet-free interval. CHCs may interfere with the metabolism of other compounds and therefore increase (cyclosporin) or decrease (lamotrigine) their plasma and tissue concentrations. Ethinylestradiol may inhibit clearance of CYP1A2 substrates leading to weak (e.g., theophylline) or moderate (e.g., tizanidine) increases in their plasma concentration. Concomitant medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (with or without ribavirin), glecaprevir/pibrentasvir may increase risk of ALT elevations, therefore switch Yacella-users to an alternative contraceptive method prior to initiation of regimens containing these products (Yacella can be restated 2 weeks after treatment completion). CHCs may influence the results of certain laboratory tests, including biochemical parameters of the liver, thyroid, adrenal and renal function, serum levels of proteins, parameters of carbohydrate metabolism, parameters of coagulation and fibrinolysis. **Pregnancy & Lactation:** Not indicated during pregnancy; treatment should be withdrawn immediately if pregnancy occurs. Not recommended during breastfeeding. Increased risk of VTE during the postpartum period should be considered when re-starting Yacella. **Effects on ability to drive & use machinery:** No studies on the effect on the ability to drive and use machinery have been performed, however, none observed for CHC users. **Adverse Events:** Common (≥1/100 to <1/10): depressed mood, headache, migraine, nausea, menstrual disorders, intermenstrual bleeding, breast pain, breast tenderness, vaginal discharge, vulvovaginal candidiasis. **Overdose:** no data available; nausea, vomiting and withdrawal bleeding (may even occur in girls before their menarche) have been reported with CHC overdose. **Refer to SmPC for full information on adverse events and overdose management. Legal Category:** POM. **Price:** 3 x 21 tablets £8.30. **Marketing Authorisation Number:** PL 20117/0360. **Marketing Authorisation Holder:** Morningside Healthcare Ltd, Unit C, Harcourt Way, Leicester, LE19 1WP United Kingdom. **Date reviewed:** June 2023. **Version number:** 10103471880 v 1.0

Please refer to full SmPC text before prescribing. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Morningside Healthcare Ltd.'s Medical Information Department on Tel: 0116 478 0322.