Bimizza® (150mcg desogestrel and 20mcg ethinylestradiol). Please refer to the full Summary of Product Characteristics (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 in the order shown on the blister pack, 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, during which 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 Bimizza, switching from a different contraceptive method, and management of missed tablets or gastrointestinal disturbances (including vomiting and diarrhoea). **Contraindications:** Pancreatitis or history thereof if associated with severe hypertriglyceridaemia. Presence or history of severe hepatic disease with currently abnormal liver function tests or liver tumours. Known or suspected estrogen-dependent tumours. Endometrial hyperplasia. Undiagnosed vaginal bleeding. Known or suspected pregnancy. 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. Presence, history, risk/high risk of, or hereditary or acquired predisposition for VTE or arterial thromboembolism (ATE), including: current VTE on anticoagulants; major surgery with prolonged immobilization; history of deep venous thrombosis, pulmonary embolism, myocardial infarction, prodromal conditions (angina pectoris or transient ischaemic attack [TIA]), stroke or migraine with focal neurology; presence of multiple risk factors for VTE or ATE or a serious risk factor for ATE (diabetes mellitus with vascular symptoms, severe hypertension or severe dyslipoproteinaemia); cerebrovascular disease (stroke). Safety and efficacy in adolescents <18 years of age has not yet been established. **Precautions & Warnings:** CHCs are associated with increased risk of VTEs, ATEs (myocardial infarction) and cerebrovascular accidents (TIAs). Bimizza may be associated with up to twice the risk of VTEs vs CHCs which contain levonorgestrel, norgestimate or norethisterone. The decision to use Bimizza should only be taken after discussion with the patient to ensure she understands the risk of VTEs, how her current risk factors influence this risk and that the VTE risk is highest in the first ever year of use (risk may also be increased when initiated after a ≥4 week break in use). If multiple risk factors for VTE or ATE are present they may constitute a contraindication; total risk should be considered before prescribing. Advise patients to seek urgent medical attention and inform the healthcare professional that they are taking a CHC if VTE symptoms occur. Refer to SmPC for full information on risk factors and symptoms of VTEs and ATEs. Women should be advised not to smoke if they wish to use a CHC; women >35 years of age should be strongly advised to use a different method of contraception if they continue to smoke. Increased risk of thromboembolism in pregnancy, particularly during the 6-week period of the puerperium must be considered. A possible increased risk of cervical cancer has been reported with long-term (>5 years) CHC use. Slightly increased risk of breast cancer has been reported in CHC users. This may be due to an earlier diagnosis, biological effects of the pill or a combination of both. The excess number of breast cancer diagnoses in current/recent CHC users is small vs overall risk of breast cancer. Age of discontinuation is the most important risk factor for breast cancer in CHC users; risk gradually declines up to 10 years after termination, at which point there appears to be no excess risk. In rare cases, hepatic tumours have been reported in users of oral contraceptives. Risk of endometrial and ovarian cancer is reduced with 50µg ethinylestradiol, whether this applies to lower-dosed CHC (including Bimizza) remains unconfirmed. Possible increased risk of breast cancer should be discussed with the user and weighed against the benefits of CHCs, taking into account the evidence that they offer substantial protection against the risk of developing certain other cancers (ovarian and endometrial). In the event of any aforementioned condition/risk factors the suitability of Bimizza should be discussed with the patient. Patients should be advised to contact their physician in the event of aggravation or first appearance of any of the aforementioned conditions so discontinuation can be considered. Presence or family history of hypertriglyceridaemia may increase risk of pancreatitis during CHC use. 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. May induce/exacerbate symptoms of hereditary and acquired 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 history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation during use. 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. Patients who develop an increase in frequency or severity of migraine should discontinue use. Take a complete history, conduct a physical examination and rule out pregnancy prior to starting or resuming CHC use. Instruct patients to read the user leaflet carefully and adhere to advice; draw attention to information on VTE/ATE, their symptoms, known risk factors and actions in the event of a suspected thrombosis. Women should be advised that hormonal contraceptives do not protect against HIV infections (AIDS) and other sexually transmitted diseases. In the event of STI/HIV risk the correct and consistent use of condoms is recommended (either alone or with another contraceptive method). As with all CHCs changes in or irregular bleeding may occur, especially during the first months of use (may include bleeding frequency, intensity or duration); 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. **Interactions:** Consult prescribing information of concomitant medications for potential interactions. Certain medications may increase CHC clearance and lead to contraceptive failure and/or breakthrough bleeding. Medicinal or herbal products that induce hepatic microsomal enzymes (cytochrome P450 enzymes; includes: phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, rifabutin and possibly: oxycarbazepine, modafinil, topiramate, felbamate, griseofulvin, some HIV protease inhibitors [e.g., ritonavir] and non-nucleoside reverse transcriptase inhibitors [e.g., efavirenz] and products containing the herbal remedy St. John's Wort) can increase clearance of sex hormones, and may decrease effectiveness of CHCs including Bimizza. Women should be advised that Bimizza efficacy may be reduced by hepatic enzyme-inducing medicinal or herbal products; a barrier contraceptive method should be used in addition to Bimizza during administration and for 28 days after discontinuation of hepatic enzyme-inducing medicinal products. 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. An alternative, unaffected method of contraception should be considered for women on long-term treatment with enzyme-inducing medicine products. Co-administration of many combinations of HIV protease inhibitors and non-nucleoside reverse transcriptase inhibitors and/or combinations with Hepatitis C virus medicinal products, can impact plasma concentrations of progestins, including etonogestrel, the active metabolite of desogestrel or estrogens. Concomitant medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (with or without ribavirin), glecaprevir/pibrentasvir may increase risk of ALT elevations. Concomitant administration of strong or moderate CYP3A4 inhibitors may also increase serum concentrations of estrogens or progestins, including etonogestrel. CHCs may interfere with the metabolism of other compounds and therefore increase (cyclosporin) or decrease (lamotrigine) their plasma and tissue concentrations. 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. Increased risk of VTE during postpartum period should be considered when re-starting Bimizza. Not recommended during breastfeeding. **Effects on ability to drive & use machinery:** No effects on ability to drive and use machines have been observed. **Adverse Events:** Common (≥1/100 to <1/10): depressed or altered mood, headache, nausea, abdominal pain, breast pain or tenderness, weight increase. Refer to SmPC for full information on adverse events. **Overdose:** No reports of serious deleterious effects; nausea, vomiting and slight vaginal bleeding have been reported with CHC overdose. **Legal Category:** POM. **Price:** 3 x 21 tablets £5.04. **Marketing Authorisation Number:** PL 20117/0091. **Marketing Authorisation Holder:** Morningside Healthcare Ltd, Unit C, Harcourt Way, Leicester, LE19 1WP United Kingdom. **Date Reviewed:** June 2023. **Version Number:** 10103471881 v1.0 June 2023.

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.