Cimizt® tablets (desogestrel and ethinylestradiol) Prescribing Information (Please refer to 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). Not indicated during pregnancy. **Available strengths**: Cimizt 150 microgram desogestrel/30microgram ethinylestradiol tablets **Dosage & Administration:** Oral use. One tablet daily, at about the same time, for 21 consecutive days, starting on Day 1 of the natural menstrual cycle. Start each subsequent pack after a 7-day tablet-free interval. A withdrawal bleed will usually occur on day 2-3 after the last tablet and may not finish before the next pack starts. Please refer to the SmPC for full advice on if menstruation has already begun, switching from a different contraceptive method to Cimizt, and management of missed tablets or gastrointestinal disturbances (including vomiting and diarrhoea). **Contraindications:** Combined hormonal contraceptives (CHCs) should not be used if any of the conditions below are present or appear for the first time during CHC use: Venous thromboembolism (VTE), deep venous thrombosis (DVT), pulmonary embolism (PE). Known predisposition for VTE (APC resistance, Factor V Leiden, antithrombin-III deficiency, protein C deficiency, protein S deficiency) or high risk due to multiple risk factors. Major surgery with prolonged immobilisation. Current, history of, or prodromal arterial thromboembolism (ATE), predisposition for (ATE) including hyperhomocysteinaemia and antiphospholipid-antibodies. High risk of (ATE) due to multiple risk factors or a serious risk factor such as diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia. Cerebrovascular disease or prodromal condition. History of migraine with focal neurological symptoms. Pancreatis or history thereof with severe hypertriglyceridemia. Presence or history of severe hepatic disease, liver tumours (benign or malignant). Known or suspected estrogen dependent tumours. Endometrial hyperplasia, undiagnosed vaginal bleeding, pregnancy, hypersensitivity to active substances or excipients. Contraindicated in concomitant use of ombitasvir/paritaprevir/ritonavir and dasabuvir, and 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. Include full discussion of individual risk factors, how VTE risk is highest during the first ever year of use, the symptoms of VTE and ATE, and advise what to do in the event of a suspected thrombosis or first appearance of risk factors. Instruct patients to read the patient information leaflet carefully and adhere to advice; draw attention to the information on VTE, and ensure the woman understands VTE risk and the relative risk of CHCs containing levonorgestrel, norgestimate or norethisterone. 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. Please consult SmPC for full information on risk factors for VTE and ATE. An increased risk of cervical cancer has been reported in some studies on long term use. There is a slightly increased relative risk of breast cancer. Patients who develop an increase in frequency or severity of migraine should discontinue 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 behavior and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment. An increased risk of cervical cancer has been reported in some studies on long term use. There is a slightly increased relative risk of breast cancer. 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. CHCs offer substantial protection against the risk of endometrial and ovarian cancer. 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 or acquired angioedema. Acute or chronic disturbances of liver function may necessitate discontinuation until liver function returns to normal. Discontinue if cholestatic jaundice previously experienced during pregnancy or sex steroid use recurs. Monitor patients with diabetes during the first months of use. Crohn's disease and ulcerative colitis have been associated with 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. 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. 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). 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. Advise women not to smoke; smokers >35 years of age should be strongly advised to use a different method of contraception. **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 Cimizt. Women should be advised that Cimizt efficacy may be reduced by hepatic enzyme-inducing medicinal or herbal products; a barrier contraceptive method should be used in addition to Cimizt 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 administration of strong or moderate CYP3A4 inhibitors may also increase serum concentrations of estrogens or progestins, including etonogestrel. Concomitant medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (with or without ribavirin), glecaprevir/pibrentasvir may increase risk of ALT elevations. 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 stopped if pregnancy occurs. Not recommended during breastfeeding. Increased risk of VTE during the postpartum period should be considered when re-starting Cimizt. **Effects on ability to drive & use machinery:** No effects have been observed. **Adverse Events: Refer to SmPC for full information on adverse events.** As with all CHCs irregular bleeding may occur, especially during the first months of use (may include bleeding frequency, intensity or duration). Common (≥1/100): depressed or altered mood, headache, nausea, abdominal pain, breast pain, breast tenderness, weight increase. **Overdose:** No serious effects have been reported with overdose. Nausea, vomiting and slight vaginal bleeding have been reported with CHC overdose. **Legal Category:** POM. **Price:** 3 x 21 tablets £3.80. **Marketing Authorisation Number:** PL 20117/0231. **Marketing Authorisation Holder:** Morningside Healthcare Ltd, Unit C, Harcourt Way, Leicester, LE19 1WP United Kingdom. **Date Reviewed:** June 2023. **Version number:** 10103471882 V 1.0 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.