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Minipil 20 film-coated tablets	<i>Following first trimester abortion</i> MINIPIL 20 use may begin immediately. Additional contraceptive measures are not needed. <i>Following delivery of second-trimester abortion</i> Because the immediate post-partum period is associated with an increased risk of thromboembolism, MINIPIL 20 use should begin no sooner than the 28th postpartum day following either delivery in a non-lactating woman or second-trimester abortion. The woman should be advised to use a non-hormonal back-up method of birth control during the first 7 days of MINIPIL 20 use. However, if intercourse has already occurred, pregnancy must be ruled out before MINIPIL 20 use is begun; otherwise, the woman must wait until her first menstrual period before beginning MINIPIL 20 use. (See Venous and Arterial Thrombosis and Thromboembolism and Lactation) <u>How to delay a period</u> To delay a menstrual period, the user should skip the tablet-free interval and immediately begin a new pack of MINIPIL 20. The delay may be continued for as long as desired up until all tablets in the new pack are taken. During the delay, the user may experience breakthrough bleeding or spotting. Regular intake of MINIPIL 20 should be resumed after the usual 7-day tablet-free interval. Management of missed tablets Contraceptive protection may be reduced if active tablets are missed, particularly if the missing of tablets extends the tablet-free interval. - If one active tablet is missed but is remembered within 12 hours of the usual dose, it should be taken as soon as it is remembered. - If one active tablet is missed and is remembered more than 12 hours after the usual dose or if two or more active tablets are missed, contraceptive protection may be reduced. The last missed tablet should be taken as soon as it is remembered, which may result in the user taking two tablets on the same day. Subsequent tablets should be taken at the usual time. A non-hormonal back-up method of birth control must be used for the next 7 days. <i>No hormonal contraceptive use within the preceding month</i> The user should begin taking MINIPIL 20 on Day 1 of her natural menstrual (i.e., the first day of menstrual bleeding). Beginning MINIPIL 20 use on days 2 – 7 of the menstrual cycle (e.g., Sunday start) is allowed; however, a non-hormonal back-up method of birth control (e.g., condom, spermicide) is recommended during the first 7 days of MINIPIL 20 use. <i>Switching from another combined oral contraceptive (COC, vaginal ring, transdermal patch)</i> Preferably, MINIPIL 20 use should begin the day after the last active tablet of the previous COC pack has been taken but no later than the day following the usual tablet-free or inactive tablet interval of the previous COC. <i>Changing from a progestogen-only-method (oral pill, injection, implant) or intrauterine device (IUD)</i> The user may discontinue use of a progestin-only pill on any day; use of MINIPIL 20 should begin the following day. MINIPIL 20 use should begin on the same day that a progestin-only implant or a progestin-only IUD is removed. MINIPIL 20 use should begin on the day that the next progestin-only injection is scheduled. In each of these situations, the user should be advised to use a non-hormonal back-up method of birth control during the first 7 days of MINIPIL 20 use.	- Hepatic adenomas or carcinomas, active liver disease, as long as liver function has not returned to normal - Known or suspected carcinoma of the breast or other known or suspected estrogen-dependent neoplasia - Disorders of lipometabolism - Thrombogenic, rhythm disorders and thrombogenic valvulopathies - Sickle-cell anemia - Diabetes with vascular involvement - Undiagnosed vaginal bleeding - Known or suspected pregnancy - Cerebrovascular or coronary artery disease - Uncontrolled hypertension - Hereditary or acquired thrombophilias - Headache with focal neurological symptoms eg. aura - Pancreatitis associated with severe hyptriglyceridemia (current or history) - Hypersensitivity to the active substances levonorgestrel, ethinylestradiol or to any of the excipients in MINIPIL 20 tablets. MINIPIL 20 is contraindicated for concomitant use with the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir (See Section Warnings and Precautions and Section Interactions with Other Medicaments). SPECIAL WARNINGS AND PRECAUTIONS FOR USE Warnings If any of the conditions/risk factors mentioned below is present, the benefits of COC use should be weighed against the possible risks for each individual and discussed with the woman before she decides to start using it. In the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors the woman should contact her physician. The physician should then decide on whether its use should be discontinued. Cigarette smoking increases the risk of serious cardiovascular adverse reactions from combined oral contraceptive (COC) use. This risk increases with age and with the extent of smoking (in epidemiology studies, smoking ≥15 cigarettes/day was associated with a significantly increased risk), and is quite marked in women >35 years. Women who use COCs should be strongly advised not to smoke. Medical precautions 1. Venous Thrombosis and Thromboembolism: Use of COCs increases the risk of venous thrombotic and thromboembolic events. Reported events include deep venous thrombosis and pulmonary embolism. For information on retinal vascular thrombosis, see Ocular Lesions in the text as follows. The use of any COC carries an increased risk of venous thrombotic and thromboembolic events compared with no use. The excess risk is highest during the 1st year a woman ever uses a COC. The risk of venous thrombotic and thromboembolic events is further increased in women with conditions predisposing for venous thrombosis and thromboembolism. Caution must be exercised when prescribing COCs for such women. Examples of predisposing conditions for venous thrombosis and thromboembolism are - Obesity - Surgery or trauma with increased risk of thrombosis - Recent delivery or 2nd trimester abortion - Prolonged immobilization - Increasing age Further 'risk' factors for the 'use' of 'COCs' are listed in Contraindications. The relative risk of postoperative thromboembolic complications has been reported to be increased 2- to 4-fold with the use of COCs. The relative risk of venous thrombosis in women with predisposing conditions is twice that of women without such conditions. If feasible, COCs should be discontinued for 4 weeks prior to and for 2 weeks after elective surgery with increased risk of thrombosis - During prolonged immobilization Because the immediate postpartum period is associated with an increased risk of thromboembolism, COC use should begin no sooner than the 28th postpartum day following either delivery in a non-lactating woman or 2nd-trimester abortion. 2. Arterial Thrombosis and Thromboembolism: The use of COCs increases the risk of arterial thrombotic and thromboembolic events. Reported events include myocardial infarction and cerebrovascular events (ischemic and hemorrhagic stroke, transient ischemic attack). For information on retinal vascular thrombosis, see Ocular Lesions. The risk of arterial thrombotic and thromboembolic events is further increased in women with underlying risk factors. Caution must be exercised when prescribing COCs for women with risk factors for arterial thrombotic and thromboembolic events. Examples of risk factors for arterial thrombotic and thromboembolic events are: - Smoking - Hypertension - Hyperlipidemias - Obesity - Increasing age COC users with migraine (particularly migraine with aura) may be at increased risk of stroke (see Contraindications). The most important risk factor for cervical cancer is persistent human papillomavirus infection. There is a continuous controversy about the extent to which such findings may be due to differences in sexual behavior and other factors. In cases of undiagnosed abnormal genital bleeding, adequate diagnostic measures are indicated. - Breast Cancer Established risk factors for the development of breast cancer include increasing age, family history, obesity, nulliparity and late age for 1st full-term pregnancy. There is a slightly increased risk of having breast cancer diagnosed in women who are using COCs compared to never-users. The increased risk gradually disappears during the course of the 10 years after cessation of COC use. The increased risk of breast cancer diagnosis may be due to earlier	detection of breast cancer in COC users (due to more regular clinical monitoring), the biological effects of COCs, or a combination of both. Hepatic Neoplasia/Liver Disease In very rare cases, hepatic adenomas and in extremely rare cases, hepatocellular carcinoma may be associated with COC use. The risk appears to increase with duration of COC use. Rupture of hepatic adenomas may cause death through intra-abdominal hemorrhage. Women with a history of COC-related cholestasis and women who develop cholestasis during pregnancy are more likely to develop cholestasis with COC use. Such patients who use COCs should be carefully monitored and the COC should be discontinued if cholestasis recurs. Hepatocellular injury has been reported with COC use. Early identification of drug-related hepatocellular injury can decrease the severity of hepatotoxicity when the drug is discontinued. If hepatocellular injury is diagnosed, patients should stop taking COC, use a non-hormonal form of birth control and consult a physician. Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until liver function has returned to normal. 4. Gallbladder Disease: Earlier studies reported an increased risk of surgically confirmed gallbladder disease in users of estrogens and oral contraceptives. However, more recent studies have shown that the relative risk of developing gallbladder disease may be minimal. 5. Blood Pressure: Increases in blood pressure have been reported in women taking COCs. In women with hypertension, history of hypertension or hypertension-related diseases (including certain renal diseases), another method of birth control may be preferable. If COCs are used in such cases, close monitoring is recommended, and if a significant increase in blood pressure occurs, COCs should be discontinued. Elevated blood pressure associated with COC use will generally return to baseline after stopping COCs, and there appears to be no difference in the occurrence of hypertension among ever- and never-users of COC. In COC-transmucosal (ALT) elevations higher than 5 times the upper limit of normal (ULN) occurred significantly more frequent in women using ethinylestradiol-containing medications such as, combined hormonal contraceptives (CHCs). Patients who are taking ethinylestradiol-containing preparations should switch to an alternative method of contraception (e.g. progestin only contraception or non-hormonal methods) prior to initiating ombitasvir / paritaprevir / ritonavir and dasabuvir therapy (See Section Contraindications and Section Interactions with Other Medicaments). 6. Ocular Lesions: COCs are associated with retinal vascular thrombosis, which may lead to partial or complete loss of vision. If there are signs or symptoms eg. visual changes, onset of proptosis or diplopia, papilledema, or retinal vascular lesions, the COC should be discontinued and the cause immediately evaluated. 7. Migraine/Headache: The onset or exacerbation of migraine or development of headache with a new pattern that is recurrent, persistent or severe requires discontinuation of COCs and evaluation of the cause. Women with migraine (particularly migraine with aura) who take COCs may be at increased risk of stroke. (See Contraindications) 8. Immune Disorders Angioedema Exogenous estrogens may induce or exacerbate symptoms of angioedema, particularly in women with hereditary angioedema. Medicalexamination/consultation Prior to the initiation or reinstitution of MINIPIL 20 a complete	medical history (including family history) should be taken and pregnancy must be ruled out. Blood pressure should be measured and a physical examination should be performed, guided by the contraindications (see Contraindications) and warnings (see Special Warnings and precautions for use). The woman should also be instructed to carefully read the user leaflet and to adhere the advice given. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman. Women should be advised that oral contraceptives do not protect against HIV infection (AIDS) and other sexually transmitted diseases. Reduced efficacy The efficacy of COCs may be reduced in the event of missed tablets vomiting or diarrhea or concomitant medication. Reduced cycle control With all COCs, irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. Therefore, the evaluation of any irregular bleeding is only meaningful after an adaptation period of about three cycles. If bleeding irregularities persist or occur after previously regular cycles, then non-hormonal cause should be considered, and adequate diagnostic measures are indicated to exclude malignancy or pregnancy. These may include curettage. In some women withdrawal bleed may not occur during the tablet-free interval. If the COC has been taken according to the directions described in Posology and method of administration, it is unlikely that the woman is pregnant. However, if the COC has not been taken according to these directions or if the first missed withdrawal bleed or if two withdrawal bleeds are missed, pregnancy must be ruled out before the COC use is continued. ALT elevations During clinical trials with patients treated for hepatitis C virus' infections (HCV) with the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir with / without ribavirin, transaminase (ALT) elevations higher than 5 times the upper limit of normal (ULN) occurred significantly more frequent in women using ethinylestradiol-containing medications such as, combined hormonal contraceptives (CHCs). Patients who are taking ethinylestradiol-containing preparations should switch to an alternative method of contraception (e.g. progestin only contraception or non-hormonal methods) prior to initiating ombitasvir / paritaprevir / ritonavir and dasabuvir therapy (See Section Contraindications and Section Interactions with Other Medicaments). INTERACTIONS WITH OTHERS MEDICINAL PRODUCTS AND OTHERS FORMS OF INTERACTION Interactions Interactions between ethinylestradiol (EE) and other substances may lead to decreased or increased serum EE concentrations, respectively. Decreased EE serum concentrations may cause an increased incidence of breakthrough bleeding and menstrual irregularities and may possibly reduce efficacy of the COC. During concomitant use of EE-containing products and substances that may lead to decreased EE serum