Abbreviated Prescribing Information – for full prescribing information, including side effects, precautions and contra-indications, see relevant Summary of Product Characteristics (SmPC)

Product Name and Composition: **Cerelle 75 microgram film-coated tablets:** 75 micrograms desogestrel. **Cilique 250/ 35 microgram tablets**: 250 micrograms of norgestimate and 35 micrograms of ethinylestradiol. **Gedarel 20/150 microgram film-coated tablets:** 20 micrograms ethinylestradiol and 150 micrograms desogestrel. **Gedarel 30/150 microgram film-coated tablets:** 30 micrograms ethinylestradiol and 150 micrograms desogestrel. **Lucette 0.03 mg/3 mg film-coated tablets:** 0.03 mg ethinylestradiol and 3 mg drospirenone. **Millinette 20/75 microgram coated tablets:** 20 micrograms ethinylestradiol and 75 micrograms gestodene. **Millinette 30/75 microgram coated tablets:** 30 micrograms ethinylestradiol and 75 micrograms gestodene. **Rigevidon coated tablets:** 30 micrograms ethinylestradiol and 150 micrograms levonorgestrel. **TriRegol coated tablets:** 30 micrograms ethinylestradiol and 50 micrograms levonorgestrel (pink tablet); 40 micrograms ethinylestradiol and 75 micrograms levonorgestrel (white tablet); 30 micrograms ethinylestradiol and 125 micrograms levonorgestrel (ochre tablet). Please refer to the relevant SmPC for a full list of excipients. **Indication:** contraception. **Cilique, Lucette, Rigevidon, Gedarel, Millinette** The decision to prescribe these products should take into consideration the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), and how the risk of VTE with these products compares with other combined hormonal contraceptives (CHCs). **Dosage and Administration:** **Cerelle:** Take tablets every day at about the same time so the interval between two tablets is always 24 hours. Take the first tablet on the first day of menstrual bleeding. A new blister is started directly the day after the previous one. For details of usage, especially if changing from another contraceptive method or where a patient misses a dose or has vomiting/diarrhoea, please refer to the SmPC. **Cilique**, **Gedarel 20/150, Gedarel 30/150, Lucette, Millinette 20/75, Millinette 30/75, Rigevidon, TriRegol:** One tablet is to be taken daily for 21 consecutive days at about the same time of day and in the order shown on the blister pack. Each subsequent pack is started after a 7-day tablet-free interval, during which time a withdrawal bleed usually occurs. For details of usage, especially where a patient either misses a dose or has vomiting/diarrhoea, please refer to the relevant SmPC. **Gedarel 20/150, Gedarel 30/150:** No data are available on safety and efficacy of desogestrel in adolescents below 18 years.**Contraindications:** Hypersensitivity to the active substances or any of the excipients, undiagnosed vaginal bleeding, presence or history of severe hepatic disease (whilst liver function tests are abnormal). **Cerelle:** Active venous thromboembolic disorder, known or suspected sex-steroid sensitive malignancies. **Cilique:** Presence or risk of venous thromboembolism (VTE); or arterial thromboembolism (ATE); high risk of arterial thromboembolism due to multiple risk factors or to the presence of one serious risk factor such as (a) diabetes mellitus with vascular symptoms, (b) severe hypertension (c) severe dyslipoproteinaemia; acute or chronic liver disease, including viral or non-viral hepatitis or severe cirrhosis, or a history of these conditions until at least 3 months after abnormal liver function tests have returned to normal; hepatic adenomas or carcinomas; known or suspected sex-steroid influenced malignancies; undiagnosed vaginal bleeding; hypersensitivity to the active substances or to any of the excipients. **Lucette:** Hypersensitivity to peanut or soya, presence or risk of VTE, or ATE, severe renal insufficiency or acute renal failure, presence or history of liver tumours (benign or malignant), known or suspected sex-steroid influenced malignancies. Should any of these conditions appear for the first time during combined oral contraceptive (COC) use, the product should be stopped immediately. **Gedarel 20/150, Gedarel 30/150:** Presence or risk of VTE, or arterial thromboembolism (ATE), pancreatitis or a history thereof if associated with severe hypertriglyceridemia, presence or history of liver tumours (benign or malignant), known or suspected sex steroid-influenced malignancies, endometrial hyperplasia, known or suspected pregnancy, concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. **Millinette 20/75, Millinette 30/75:** presence or risk of VTE, or ATE, serious or recent hepatic disorders as long as liver function tests are not normalised, present or previous pancreatitis if associated with serious hypertriglyceridaemia, known or suspected sex steroid influenced malignant conditions of the breasts or genital organs, concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. **Rigevidon:** Presence or history of venous or arterial thrombosis, cerebrovascular disease, migraine with focal neurological symptoms, hormone dependent malignant tumour, concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. **TriRegol:** Presence or history of venous or arterial, present or previous prodromal symptoms of thrombosis, pregnancy or suspected pregnancy, cardiovascular disorders severe hypertension, diabetes complicated with angiopathy, ocular disorder of vascular origin, malignant tumours in breast, malignant endometrial tumours or other known or suspected oestrogen dependent neoplastic disorder, present or previous benign or malignant liver tumours, history of migraines with focal neurological symptoms, concomitant use with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir. **Warnings and Precautions:** Prior to starting or resuming use a complete history should be taken, physical examination performed and pregnancy ruled out. The woman should be instructed to carefully read the user leaflet and adhere to the advice. It is important to draw attention to the information on VTE and ATE, including the risk of using these products compared with other CHCs, the symptoms of VTE and ATE, the known risk factors and what to do 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. The benefits of use must be weighed against possible risks in each individual case and discussed with the woman. Efficacy may be reduced in the event of missed tablets, gastro-intestinal disturbances or concomitant medication – see relevant SmPC for details. **Cerelle:** The risk of breast cancer is slightly increased with COC use, but for progestogen-only contraceptives the evidence is less conclusive. A benefit/risk assessment should be made in women with liver cancer as a biological effect of progestogens cannot be excluded. Cerelle should be discontinued in the event of a thrombosis and women with a history of thrombo-embolic disorders should be made aware of the possibility of a recurrence. Discontinuation of Cerelle should also be considered if there is long-term immobilization. Diabetic patients should be carefully observed during the first months of use due to a potential effect on insulin resistance and glucose tolerance. If sustained hypertension develops, or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, consider discontinuing Cerelle. Ectopic pregnancy should be included in the differential diagnosis if a woman develops amenorrhoea or abdominal pain. Chloasma may occasionally occur, and women with a tendency to this should avoid exposure to the sun or UV radiation whilst taking Cerelle. The following conditions have been reported during sex steroid use: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema. Cerelle contains lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Cilique:** Blood pressure should be measured prior to starting or resuming use. In the case of undiagnosed, persistent or recurrent abnormal vaginal bleeding, rule out malignancy. If bleeding irregularities persist beyond three cycles or occur after previously regular cycles, further diagnostic procedures should be considered. Conditions requiring supervision: breast feeding; increased risk of VTE or ATE (please refer to the SmPC for a list of risk factors and symptoms for VTE and ATE); adequately controlled hypertension (persistently elevated baseline systolic values 140-159 mm Hg or diastolic values 90-94 mm Hg); obesity (BMI ≥ 35 kg/m^2); history of cholestasis (related to COCs), current or medically treated gallbladder disease, porphyria; history of breast cancer, 5 years disease-free. The increased risk of thromboembolism in pregnancy, and particularly the 6 week period of the puerperium, must be considered. A hepatic tumour should be considered in the differential diagnosis when upper abdominal pain, enlarged liver or signs of intra-abdominal haemorrhage occur. A slightly increased relative risk of breast cancer has been observed in COC users, although direct causation has not been shown. A possible increased risk of cervical cancer has been reported with long-term COC use. If bleeding irregularities persist beyond three cycles or occur after previously regular cycles, further diagnostic procedures should be considered. Women with hypertriglyceridaemia, or a family history thereof, may be at an increased risk of pancreatitis when using CHCs. Oral contraceptives may cause a decrease in glucose tolerance; pre-diabetic and diabetic women in particular should be carefully monitored while taking oral contraceptives. Consider the risks associated with the following before prescribing oral contraceptives: asymptomatic gall bladder disease or cholecystectomy;

benign liver tumours; migraine without focal aura (the onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent or severe requires discontinuation of oral contraceptives and evaluation of the cause). Crohn's disease and ulcerative colitis have been associated with CHC use. Chloasma may occasionally occur, and women with a tendency to this should avoid exposure to the sun or UV radiation whilst taking Cilique. Cilique contains lactose and should not be taken by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Gedarel 20/150, Gedarel 30/150, Lucette, Millinette 20/75, Millinette 30/75, Rigevidon, TriRegol:** ***Circulatory disorders:*** The use of any CHC increases the risk of VTE compared with no use. Products that contain levonorgestrel, norgestimate or norethisterone are associated with the lowest risk of VTE. Other products may have up to twice this level of risk. The decision to use any product other than one with the lowest VTE risk should be taken only after a discussion with the woman to ensure she understands the risk of VTE, how her current risk factors influence this risk, and that her VTE risk is highest in the first ever year of use. There is also some evidence that the risk is increased when a CHC is re-started after a break in use of 4 weeks or more. The risk of arterial thromboembolic complications or of a cerebrovascular accident in CHC users increases in women with risk factors. If a woman has more than one risk factor, it is possible that the increase in risk is greater than the sum of the individual factors - in this case her total risk should be considered. If the balance of benefits and risks is considered to be negative a CHC should not be prescribed. Please refer to the relevant SmPC for a list of risk factors and symptoms for VTE and ATE. CHC users should be specifically advised to contact their physician in case of possible symptoms of thrombosis. In case of suspected or confirmed thrombosis, COC use should be discontinued. ***Tumours:*** A possible increased risk of cervical cancer has been reported with long-term COC use. A slightly increased relative risk of breast cancer has been observed in COC users, although direct causation has not been shown. Hepatic tumours (benign and malignant) have also been reported. ***Other conditions:*** Possible increased risk of pancreatitis in women with family history of, or current, hypertriglyceridaemia. Clinically relevant increases in blood pressure may rarely occur and require discontinuation of COC use. If pre-existing or emergent elevated blood pressure does not respond adequately to antihypertensive therapy, COC must be withdrawn and only resumed if normotensive values are achieved. Liver function disturbance (acute or chronic) may require COC discontinuation until liver function markers are normal. COCs may have an influence on peripheral insulin resistance and glucose tolerance; diabetics should be closely monitored during COC use. Depression and worsening of endogenous depression, epilepsy, Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation while taking COCs. With all COCs, irregular bleeding may occur, especially during the first months of use. The evaluation of any irregular bleeding should be considered after approximately three cycles. If bleeding irregularities occur after previously regular cycles, further diagnostic procedures should be considered. Please refer to the relevant SmPC for further information regarding cycle control. **Lucette:** Check serum potassium during first treatment cycle in patients with renal insufficiency and pre-treatment serum potassium in the upper treatment range, and particularly during concomitant use of potassium sparing medicinal products. In women with hereditary angioedema exogenous oestrogens may induce or exacerbate symptoms of angioedema. Contains soya lecithin, therefore patients with hypersensitivity to peanut or soya should not take this medicine. **Gedarel 20/150, Gedarel 30/150:** Contains lactose, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take these products. In patients treated with ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, transaminase (ALT) elevations higher than 5 times the upper limit of normal (ULN) occurred significantly more often in women using ethinylestradiol-containing medications; Gedarel users must switch to an alternative method of contraception (e.g. progestagen-only contraception or non-hormonal methods) prior to starting therapy with this combination drug regimen. Gedarel can be restarted 2 weeks following completion of treatment with this combination drug regimen. **Millinette 20/75 Millinette 30/75, Rigevidon, TriRegol:** Hyperlipidaemic women should be closely monitored. Contains lactose and sucrose, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption or with rare hereditary problems of fructose intolerance should not take these products. In patients treated with ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, transaminase (ALT) elevations higher than 5 times the upper limit of normal (ULN) occurred significantly more often in women using ethinylestradiol-containing medications; Millinette / Rigevidon / TriRegol users must switch to an alternative method of contraception (e.g. progestagen-only contraception or non-hormonal methods) prior to starting therapy with this combination drug regimen. Millinette / Rigevidon / TriRegol can be restarted 2 weeks following completion of treatment with this combination drug regimen. **Undesirable effects:** Prescribers should consult the relevant SmPC in relation to other adverse reactions **Cerelle:** The most commonly reported is bleeding irregularity (up to 50% of women using desogestrel). Common (≥1/100 to <1/10): mood altered, libido decreased, depressed mood, headache, nausea, acne, breast pain, menstruation irregular, amenorrhoea, weight increased. The following serious undesirable effects have also been reported: ectopic pregnancy, venous and arterial thromboembolic disorders, hormone-dependent tumours (e.g. liver tumours, breast cancer), chloasma, (aggravation of) angioedema and/or aggravation of hereditary angioedema. **Cilique:** Very common (>1/10): headache, gastrointestinal disorder, vomiting, diarrhoea, nausea, dysmenorrhoea, metrorrhagia, abnormal withdrawal bleeding. Common (>1/100 to <1/10): urinary tract infection, vaginal infection, hypersensitivity, fluid retention, weight increased, mood altered, depression, nervousness, insomnia, migraine, dizziness, gastrointestinal pain, abdominal pain, abdominal distension, constipation, flatulence, acne, rash, muscle spasms, pain in extremity, back pain, amenorrhoea, genital discharge, breast pain, chest pain, oedema, asthenic conditions. **Gedarel 20/150, Gedarel 30/150:** Very common (≥1/10): irregular bleeding. Common (≥1/100 to <1/10): depressed mood, mood altered, headache, dizziness, nervousness, nausea, abdominal pain, acne, amenorrhoea, breast pain, breast tenderness, dysmenorrhoea, premenstrual syndrome, weight increased. The following serious undesirable effects have also been reported: increased risk of arterial and venous thrombotic and thrombo-embolic events (including myocardial infarction, stroke, transient ischemic attacks, venous thrombosis and pulmonary embolism), hypertension, hormone-dependent tumours (e.g. liver tumours, breast cancer), chloasma. **Lucette:** Common (≥1/100 to <1/10): depressive mood, headache, migraine, nausea, menstrual disorders, intermenstrual bleeding, breast pain, leucorrhoea, breast tenderness, vaginal moniliasis. The following serious undesirable effects have also been reported: increased risk of arterial and venous thrombotic and thrombo-embolic events (including myocardial infarction, stroke, transient ischemic attacks, venous thrombosis and pulmonary embolism), hypertension, liver tumours, occurrence or deterioration of conditions for which association with COC use is not conclusive (Crohn's disease, ulcerative colitis, epilepsy, migraine, uterine myoma, porphyria, systemic lupus erythematosus, herpes gestationis, Sydenham's chorea, haemolytic uraemic syndrome, cholestatic jaundice), chloasma, acute or chronic disturbances of liver function, induction or exacerbation of angioedema in women with hereditary angioedema, breast cancer. **Millinette 20/75, Millinette 30/75:** Very common (≥1/10): headache, spot bleeding, breakthrough bleeding Common (≥1/100 to <1/10): nervousness, dizziness, breast tenderness, breast pain, breast swelling, breast secretion, dysmenorrhea, amenorrhoea, vaginitis including candidiasis, changes in vaginal secretion, nausea, abdominal pain, acne, depression/mood swings, weight increase. The following serious undesirable effects have also been reported: increased risk of arterial and venous thrombotic and thrombo-embolic events cervical cancer, liver tumours, chloasma, breast cancer abdominal pain, acne, amenorrhoea, irritability, weight increase. **Rigevidon:** Common (>1/100, <1/10): vaginitis including vaginal candidiasis, mood swings including depression, altered libido, nervousness, dizziness, nausea, vomiting, abdominal pain, acne, breast pain, stress, swelling and secretions, dysmenorrhoea, altered periods, altered ectropion and vaginal secretions, amenorrhoea, water retention/oedema, altered weight. The following serious undesirable effects have also been reported: venous thromboembolic disorders (i.e. deep leg or pelvic venous thrombosis and pulmonary embolism), arterial thromboembolic disorders, hypertension, cervical cancer, liver tumours, skins and subcutaneous disorders: chloasma, erythema nodosum, Crohn's disease, ulcerative colitis, porphyria, systemic lupus erythematosus, herpes gestationis, Sydenham's chorea, haemolytic uremic syndrome, cholestatic jaundice. **TriRegol:** Common (≥1/100 to <1/10): depression, mood altered, nausea, abdominal pain, cholelithiasis, acne, chloasma, breast tenderness, breast pain, metrorrhagia, weight increased. The following serious undesirable effects have also been reported: breast cancer, hepatic adenoma, hepatic neoplasm malignant, hyperlipidaemia, hypercholesterolaemia, hypertriglyceridaemia, cerebrovascular accident, cerebrovascular disorder, epilepsy aggravated, migraine, myocardial infarction, hypertension, venous embolism, arterial embolism, pulmonary embolism, ulcerative colitis, Crohn's disease, pancreatitis, systemic lupus erythematosus. **NHS**

Price: **Cerelle** 3 x 28 tablets £3.50**; Cilique** 3 x 21 tablets £4.65; **Gedarel 20/150** 3 x 21 tablets £5.08**; Gedarel 30/150** 3 x 21 tablets £4.19**; Lucette** 3 x 21 tablets £9.35**; Millinette 20/75** 3 x 21 tablets £5.41**; Millinette 30/75** 3 x 21 tablets £4.12**; Rigevidon** 3 x 21 tablets £1.89**; TriRegol** 3 x 21 tablets £2.43**. Legal Category:** POM**. Marketing Authorisation Numbers: Cerelle** PL 04854/0124; **Cilique** PL 24837/0058; **Gedarel 20/150** PL 04854/0060; **Gedarel 30/150** PL 04854/0061; **Lucette** PL 04854/0095; **Millinette 20/75** PL 04854/0122; **Millinette 30/75** PL 17550/04854/0121; **Rigevidon** PL 04854/0120; **TriRegol** PL 17550/0031. **Marketing Authorisation Holder: Cerelle, Gedarel 20/150, Gedarel 30/150, Lucette, Millinette 20/75, Millinette 30/75, Rigevidon:** Gedeon Richter Plc. 1103 Budapest, Gyömrői út, 19-21, Hungary. **Cilique:** Consilient Health Limited, 5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland **TriRegol:** Medimpex France SA, 1–3 rue Caumartin, 75009 Paris, France. Further information is available on request from Consilient Health (UK) Ltd, No.1 Church Road, Richmond upon Thames, Surrey. TW9 2QE or drugsafety@consilienthealth.com. **Date of Preparation of PI:** March 2018 UK/OCS/0318/0211

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Consilient Health (UK) Ltd, No. 1 Church Road, Richmond upon Thames, Surrey TW9 2QE UK or drugsafety@consilienthealth.com.