PRESCRIBING INFORMATION

Combined 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: Azalia 75 microgram film-coated tablets: 75 micrograms desogestrel. **Cilique** 250/ 35 microgram tablets: 250 micrograms of norgestimate and 35 micrograms of ethinylestradiol **Elvina 0.03mg/3mg Film-coated Tablets:** 0.03 mg ethinylestradiol and 3 mg drospirenone. **Elvinette 0.02mg/3mg film-coated tablets:** 0.02 mg ethinylestradiol and 3 mg drospirenone. **Ovreena 30 micrograms/150 micrograms coated tablets:** 150 micrograms levonorgestrel and 30 micrograms ethinylestradiol, **Violite 100/20:** 100 mg levonorgestrel and 20 mg ethinylestradiol. Please refer to the relevant Summary of Product Characteristics (SmPC) for a full list of excipients. **Indication:** Contraception. **Administration: Azalia:** 1 tablet taken every day at about the same time, without taking any notice of possible bleeding. Each new pack to be started directly after the previous one. The first tablet should be taken on the first day of menstrual bleeding. For details of usage, especially if changing from another contraceptive method or where a patient either misses a dose or has vomiting/diarrhoea, please refer to the SmPC. **Elvina, Elvinette, Ovreena, Violite & Cilique:** The tablets must be taken every day at about the same time in the order shown on the blister pack. One tablet is to be taken daily for 21 consecutive days. Each subsequent blister started after a 7-day tablet-free interval, during which time a withdrawal bleed usually occurs. This bleeding usually starts on day 2-3 after the last tablet and may not have stopped before the next pack is started. For details of usage, especially if changing from another contraceptive method or where a patient either misses a dose or has vomiting/diarrhoea, please refer to the relevant the SmPC. **Contraindications:** Hypersensitivity to the active substances or any of the excipients, undiagnosed vaginal bleeding, presence or history of sever e hepatic disease (whilst liver function tests are abnormal). Or with the medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir **Azalia:** 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. **Elvina & Elvinette:** Hypersensitivity to peanut or soya, presence or risk of VTE, presence or risk of arterial thromboembolism (ATE), severe renal insufficiency or acute renal failure, presence or history of liver tumours (benign or malignant), known or suspected sex-steroid influenced malignancies (e.g. of the genital organs or the breasts). **Ovreena & Violite:** Presence or history of venous or arterial thrombosis (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction (MI) or cerebrovascular disorder), the presence of severe or multiple risk factors for venous or arterial thrombosis, previous prodromal symptoms of thrombosis (e.g. transient cerebral ischaemia or angina pectoris), cardiovascular disorders (e.g. cardiac diseases, valvulopathy, arrhythmic disturbances), severe hypertension, diabetes mellitus with vascular involvement, ocular disorder of vascular origin, known or suspected sex-steroid influenced malignancies (e.g. of the genital organs or the breast) present or history of benign or malignant liver tumours, migraine with focal neurological symptoms. **Warnings and Precautions: Azalia:** The benefits of progestogen use should be weighed against the possible risks for each individual woman. The risk of breast cancer is slightly increased with COC use, but for POPs the evidence is less conclusive. A benefit/risk assessment should be made in women with liver cancer since progestogens may affect this. Women should be referred to a specialist if acute or chronic disturbances of liver function occur. **Azalia** should be discontinued in the event of a thrombosis and women with a history of thromboembolic disorders should be made aware of the possibility of a recurrence. Discontinuation 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 use. Ectopic pregnancy should be included in the differential diagnosis if a woman gets 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 **Azalia.** 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. **Cilique, Elvina, Elvinette, Ovreena & Violite:** 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. **Azalia & Cilique** contain lactose. **Tumours:** A possible increased risk of cervical cancer has been reported with long-term COC use. A slightly increased risk of breast cancer has been observed in COC users, although direct causation has not been shown. Hepati c tumours (benign and malignant) have also been reported. **Other conditions:** Possible increased risk of pancreatitis in women with family history of, or current, hypertriglyceridemia. 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, the COC must be withdrawn, and may be resumed if normotensive values are achieved. The following conditions may arise or worsen during use of COCs although evidence of a relationship is inconclusive: Jaundice and/or pruritus associated with cholestasis, gallstones, porphyria, system lupus erythematosus, haemolytic uraemic syndrome, Sydenham's chorea, herpes gestationis, hearing loss due to otosclerosis. Liver function disturbance (acute or chronic) may require COC discontinuation until liver function markers return to normal. COCs may have an influence on the peripheral insulin resistance and glucose tolerance; diabetics should be closely monitored, particularly in the early stage of COC use. Worsening of endogenous depression, epilepsy, Crohn's disease and ulcerative colitis have been reported during COC use. 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. **Azalia,Cilique, Violite & Ovreena:** 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. **Elvina, Elvinette:** 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 so ya should not take Elvina, Elvinette. **Ovreena &Violite:** Hyperlipidaemic women should be closely monitored. Contains lactose and sucrose, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucos e- galactose malabsorption or with rare hereditary problems of fructose intolerance should not take these medicines. **Interactions:** Interactions between hormonal contraceptives and other medicinal products may lead to breakthrough bleeding and/or contraceptive failure. **Azalia:** Products that induce microsomal enzymes can result in increased clearance of sex hormones, so women taking these should use a barrier method in addition to Azalia during the time of concomitant drug administration and f or 28 days after their discontinuation. For women on long-term therapy with hepatic enzyme inducers, a non-hormonal method contraception should be considered. During treatment with medical charcoal, the contraceptive efficacy of Azalia may be reduced. Under these circumstances, follow the missed pill advice. The prescribing information of concomitant medications should be consulted for potential interactions. **Elvina, Elvinette, Ovreena , Violite & Cilique:** Interactions can occur with drugs that induce hepatic enzymes which can result in increased clearance of sex hormones (e.g. phenytoin, barbiturates, primidone, carbamazepine and rifampicin; bosentan and HIV-medication (e.g. ritonavir, nevirapine) and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin and products containing the herbal remedy St. John's Wort. Contraceptive failures have al so been reported with antibiotics, such as penicillins and tetracyclines. The mechanism of this effect has not been elucidated but may include interference with the enterohepatic circulation. Additional use of a barrier method of contraception is recommended during short-term treatment with any of the above-mentioned medicines and for 7 days after its discontinuation (28 days if given rifampicin). If concomitant administration runs beyond the end of the tablets in the COC blister pack, the next pack should be started without the usual tablet-free interval. In women on long-term treatment with liver enzyme inducers, another reliable, non- hormonal, method of contraception is recommended. **Undesirable effects: Azalia:** The most commonly reported is bleeding irregularity but after two months of treatment, bleeding tends to become less frequent. The following adverse reactions have been reported: Common (≥1/100 to <1/10): mood altered, libido decreased, depressed mood, headache, nausea, acne, breast pain, menstruation irregular, amenorrhoea, weight increased. Uncommon (≥1/1,000 to <1/100): Vagina l infection, contact lens intolerance, vomiting, alopecia, dysmenorrhoea, ovarian cyst, fatigue, Rare (≥1/10,000 to <1/1,000): rash, urticaria, erythema nodosum. Breast discharge may occur during use of Azalia. Rarely ectopic pregnancies have been reported . **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. **Elvina, Elvinette & Ovreena:** In patients treated for hepatitis C virus infections (HCV) with the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin, transaminase (ALT) elevations higher than 5 times the upper limit of normal (ULN) has been observed. **Elvina:** The following adverse drug reactions have been reported during combined use of drospirenone and ethinylestradiol in clinical trials: Common (>1/100 to <1/10): depressive mood, headache, migraine, nausea, menstrual disorders, intermenstrual bleeding, breast pain, leucorrhoea, breast tenderness, vaginal moniliasis. Uncommon (>1/1,000 to <1/100): hypertension, hypotension, vomiting, diarrhoea, acne, eczema, pruritus alopecia, breast enlargement, changes in libido, vaginitis, fluid retention, body weight changes. Rare (>1/10,000 to <1/1,000): hypersensitivity, asthma, hypacusis, venous thromboembolism, arterial thromboembolism, erythema nodosum, erythema multiforme, breast secretion. **Elvinette:** Common (≥1/100 to <1/10): Emotional lability, headache, abdominal pain, acne, breast pain, breast enlargement, breast tenderness, dysmenorrhea, metrorrhagia; Uncommon (≥1/1000 to <1/100): Candidiasis, herpes simplex, allergic reaction, increased appetite, depression, nervousness, sleep disorder, paresthesia, vertigo, visual disturbance, extrasystoles, tachycardia, hypertension, hypotension, migraine, varicose veins, pharyngitis, nausea, vomiting, gastroenteritis, diarrhoea, constipation, gastrointesti nal disorder, angioedema, alopecia, eczema, pruritus, rash, dry skin, seborrhea, skin disorder, neck pain, pain in extremity, muscle cramps, cystitis, breast neoplasm, fibrocystic breast, galactorrhea, ovarian cyst, hot flushes, menstrual disorder, amenorrhea, menorrhagia, vaginal candidiasis, vaginitis, genital discharge, vulvovaginal disorder, vaginal dryness, pelvic pain, papanicolaou smear suspicious, libido decreased, edema, asthenia, pain, excessive thirst, sweating increased, weight decrease; Rare (≥1/10,000 to <1/1,000): asthma, hypacusis, venous thromboembolism, arterial thromboembolism, erythema nodosum, erythema multiforme. **Ovreena:** The most commonly reported is bleeding irregularity but after two months of treatment, bleeding tends to become less frequent. The following adverse reactions have been reported: Common (≥1/100 to <1/10): mood altered, depressed mood, depression, irritability, headache, nervousness, visual disturbances nausea, abdominal pain, acne, breast tenderness, breast pain, hypomenorrhoea, irregular bleeding, amenorrhoea, weight increased. Uncommon (≥1/1,000 to <1/100): Breast cancer, hepatic adenoma, hepatocellular carcinoma, cervical cancer, lupus erythematous, fluid retention, hyperlipidaemia, libido decreased, migraine, chorea, hypertension, VTE, arterial thromboembolic disorders, vomiting, diarrhoea, cholelithiasis, pancreatitis, rash, uticaria, chloasma and breast enlargement. Rare (≥1/10,000 to <1/1,000): Hypersensitivity, libido increased, contact lens intolerance, erythema nodosum, erythema multiforme, breast discharge, vaginal discharge and weight decreased. Violite: The most frequently reported adverse events in women using Violite are headache, including migraines, dysmenorrhoea, abdominal pain, nausea, and breakthrough bleeding/spotting. The following adverse reactions have been reported: Common (≥1/100 to <1/10): Depressed or altered mood, headache, dizziness, nausea, abdominal pain, breast pain, breast tenderness and weight increased. Uncommon (≥1/1,000 to <1/100): Fluid retention, libido decreased, migraine, aggravation of varicose veins, vomiting, diarrhoea, rash, uticaria & breast hypertrophy. Rare (≥1/10,000 to <1/1,000): Hypersensitivity, libido increased, contact lens intolerance, VTE, ATE, erythema nodosum, erythema multiforme, vaginal discharge, breast discharge and weight decreased. **Legal category:** POM. **Marketing Authorisation number: Azalia:** PA 1330/010/001 **Cilique** PA 1876/003/001; **Elvina:** PA 1330/007/001 **Elvinette:** PA 1330/008/001. **Ovreena:** PA 1330/015/001 **Violite:** PA 1876/006/001. **Marketing Authorisation Holder: Azalia, Elvina, Elvinette, Ovreena:** Gedeon Richter Plc, Gyömrői út 19-21, 1103 Budapest, Hungary, **Cilique & Violite:** Consilient Health Limited. Further information is available on request from Consilient Health Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14 or drugsafety@consilienthealth.com. AE phone number:012057766 **Date of preparation of PI:** April 2019; IE/OCS/1117/0070(2).

Health care professionals should report any suspected adverse events to HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2 Tel: 01 6764971, or at www.hpra.ie, email: medsafety@hpra.ie Suspected adverse events should also be reported to Consilient Health Ltd., Tel: 01 2057766 or drugsafety@consilienthealth.com

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REFERENCES ARE ON NEXT PAGE

Consilient Health

Abbreviated Prescribing Information – for full prescribing information, including side effects, precautions and contra-indications, see Summary of Product Characteristics (SmPC)
Product name: Prevenelle 1500 microgram tablet.
Composition: Each tablet contains 1500 micrograms of levonorgestrel. **Indication:** Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method. **Dosage and administration:** One tablet should be taken, as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse. If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately. Prevenelle can be used at any time during the menstrual cycle unless menstrual bleeding is overdue. Prevenelle is not recommended in children and very limited data are available in those under 16 years. For use after certain medications a double dose may be required. (See full SmPC) **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method. Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse >72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with levonorgestrel following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by >5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded. If pregnancy occurs after levonorgestrel treatment, consider the possibility of an ectopic pregnancy. Levonorgestrel is not recommended in patients at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) or in those with severe hepatic dysfunction. Severe malabsorption syndromes e.g. Crohn's disease, may reduce levonorgestrel efficacy. Prevenelle contains lactose monohydrate, therefore patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine. After Prevenelle, menstrual periods are usually normal and occur at the expected date +/- a few days. Women should be advised to make a medical appointment to initiate or adopt a method of regular contraception. If no withdrawal bleed occurs in the next pill-free period following the use of levonorgestrel after regular hormonal contraception, pregnancy should be ruled out. Repeated administration within a menstrual cycle is not advisable due to possible disturbance of the cycle. Limited and inconclusive data suggest that there may be reduced efficacy of Prevenelle with increasing body weight or BMI. Levonorgestrel is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception. Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases. **Interaction with other medicinal products and other forms of interaction:** The metabolism of levonorgestrel is enhanced by concomitant use of mainly CYP3A4 liver enzyme inducers by up to 50%. For women who have taken such medications during the past 4 weeks other forms of contraception are required. (See SmPC for the full list). **Undesirable effects:** Very common (≥10%): Headache, nausea, abdominal pain lower, bleeding not related to menses, fatigue; Common (≥1% to <10%): Dizziness, diarrhoea, vomiting, delay of menses >7 days, menstruation irregular, breast tenderness; Very rare (<1/10,000): Abdominal pain, rash, urticaria, pruritus, pelvic pain, dysmenorrhoea, face oedema. **Legal classification: P. Marketing Authorisation number:** PA0818/004/002. **Marketing Authorisation holder:** Medimpex (UK) Limited 127 Shirland Road, London W9 2EP England. **Further information** is available on request from Consilient Health Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14 or drugsafety@consilienthealth.com. **Date of preparation of PI:** March 2019; IE/PV/1216/0002(1).

Healthcare professionals should report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Suspected adverse reactions should also be reported to Consilient Health Ltd, Block 2A Richview Office Park, Clonskeagh, Dublin 14, 01-205-7766 or drugsafety@consilienthealth.com

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For further information and patient support visit www.knowyourcontraceptives.ie

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Gedeon Richter

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