**Microgynon® 30 & Microgynon® 30 ED, sugar coated tablets (levonorgestrel / ethinylestradiol) Prescribing Information**(Refer to the Summary of Product Characteristics (SmPC) before prescribing)

Presentation:
Microgynon® 30 Memo-strip of 21 beige, active tablets, each containing 30*g ethinylestradiol and 150*g levonorgestrel. Microgynon® 30 ED: 28 day memo strips; 21 beige, active tablets (each containing 150*g levonorgestrel & 30*g ethinylestradiol), 7 white placebo tablets.
Indication(s): Oral contraception & the recognised gynaecological indications for such oestrogen/progestogen combinations. The decision to prescribe should consider the individual woman's current risk factors, particularly those for venous thromboembolism (VTE), & how the risk of VTE with Microgynon compares with other combined hormonal contraceptives (CHCs).
Posology & method of administration: Microgynon® 30: Adults: One tablet daily, starting on the first day of the menses (or on the day after stopping another CHC). An interval of 7 days precedes each subsequent 21-day course. Microgynon® 30 ED: Adults: One tablet daily, (21 active tablets taken followed by 7 placebo tablets) starting on first day of menses (or on the day after stopping another CHC). Contraceptive protection begins immediately. Incorrect administration, GI upset or interaction with specific drugs will necessitate additional non-hormonal contraceptive measures. Children & adolescents (<18 years): Not applicable. Please consult SmPC for more information on changing treatment & special circumstances.
Contra-indications: Do not use in the following conditions & stop use immediately if any appear for the first time during use: Presence or risk of VTE: current VTE or history of DVT or PE, known hereditary or acquired predisposition for VTE, major surgery with prolonged immobilisation, a high risk of VTE due to the presence of multiple risk factors. Presence or risk of arterial thromboembolism (ATE): current or history of ATE or prodromal condition; cerebrovascular disease – current stroke, history of stroke or prodromal condition; known hereditary or acquired predisposition for ATE, such as hyperhomocysteinaemia & anti-phospholipid antibodies; history of migraine with focal neurological symptoms; high risk of ATE due to multiple risk factors or presence of one serious risk factor such as: diabetes mellitus with vascular symptoms, severe hypertension, severe dyslipoproteinaemia; presence or history of severe hepatic disease, e.g. active viral hepatitis & severe cirrhosis, as long as liver function values have not returned to normal; presence or history of liver tumours (benign or malignant); current or history of breast cancer; hypersensitivity to the active substance(s) or to any of the excipients. Concomitant use with medicinal products containing ombitasvir / paritaprevir / ritonavir, dasabuvir, glecaprevir/pibrentasvir and ofosbuvir/velpatasvir/voxilaprevir. Also consult relevant UK clinical guidance. Warnings & precautions: In the presence of the following conditions or risk factors or in the event of aggravation or first appearance of any of these conditions or risk factors, the suitability of Microgynon should be discussed with the woman or discontinuation considered. Risk of VTE: 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. Decision to use Microgynon should be taken after discussion with the woman to ensure she understands the risk of VTE with Microgynon, how her current risk factors influence this risk, & 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. VTE may be fatal in 1-2% of cases. Extremely rarely, thrombosis has been reported to occur in CHC users in other blood vessels, e.g. hepatic, mesenteric, renal or retinal veins & arteries. Risk for VTE complications in CHC users may increase substantially in a woman with additional risk factors, particularly if there are multiple risk factors. Microgynon is contraindicated if a woman has multiple risk factors that put her at high risk of venous thrombosis. Total risk of VTE should be considered as increase in risk may be greater than sum of individual factors. If benefit/risk balance is negative a CHC should not be prescribed. For a list of VTE risk factors and symptoms consult the full SmPC. Risk of ATE: epidemiological studies have associated use of CHCs with an increased risk for ATE. ATE events may be fatal. Risk of ATE complications or of a cerebrovascular accident in CHC users increases in women with risk factors. Microgynon is contraindicated if a woman has one serious or multiple risk factors for ATE that puts her at high risk of arterial thrombosis. The total risk of ATE should be considered as increase in risk may be greater than sum of individual factors. If benefit/risk balance is negative a CHC should not be prescribed. For a list of ATE risk factors and symptoms consult the full SmPC. Some studies suggest increased risk of cervical & breast cancer. Hepatic tumours have been reported with isolated cases of life-threatening intra-abdominal haemorrhages. Possible increase in risk of pancreatitis if presence or family history of hypertriglyceridaemia. Following conditions may occur or deteriorate: jaundice/pruritus related to cholestatis, gallstones, SLE, herpes gestationis, otosclerosis-related hearing loss, sickle cell anaemia, renal dysfunction, hereditary angioedema, porphyria, cervical cancer & any other condition an individual woman has experienced worsening of during pregnancy or previous use of COCs. Angioedema: Exogenous oestrogens may induce or exacerbate symptoms of hereditary and acquired angioedema. Advise women to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating treatment. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. If tendency to chloasma present advise avoidance of sun/UV. No requirement to alter regimen in diabetics, but monitor carefully. Microgynon contains lactose & sucrose. In trials with patients treated for HCV with products containing ombitasvir / paritaprevir / ritonavir and dasabuvir, with or without ribavirin, ALT elevations higher than 5 times ULN occurred significantly more frequently in women using ethinylestradiol-containing medications. ALT elevations have also been observed with HCV anti-viral medicinal products containing glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir. Interactions: Interaction with specific drugs may necessitate use of additional barrier contraception or alternative method of contraception. Microgynon may also affect the metabolism of other medicines & some lab tests. Concomitant use with medicinal products containing ombitasvir/ paritaprevir / ritonavir, dasabuvir, with or without ribavirin, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, may increase the risk of ALT elevations, therefore patients must switch to an alternative method of contraception prior to starting these drug regimens. Pregnancy & lactation: Do not use. If pregnancy occurs stop use immediately. Use during lactation may lead to reduction in the volume & composition of milk produced. Consider increased risk of VTE during the postpartum period when re-starting Microgynon. Undesirable effects: common: nausea, abdominal pain, weight increased, headache, depressed or altered mood, breast pain or tenderness Serious: cf. CI/W&P - in addition: VTE, ATE, strokes, hypertension, breast cancer, liver tumours (benign & malignant). Prescribers should consult the SmPC in relation to other side effects. Overdose: Symptoms may include nausea, vomiting & withdrawal bleeding. No antidotes. Treatment should be symptomatic. Legal Classification: POM Package Quantities & Basic NHS Costs: Microgynon 30: 3 x 21 tabs = £2.82, Microgynon 30 ED: 3 x 28 tabs = £2.54 MA Number(s): Microgynon 30: PL00010/0545 Microgynon 30 ED: PL00010/0546 Further information available from: Bayer plc, 400 South Oak Way, Green Park, Reading, RG2 6AD, UK. Tel. 0118 206 3000. Date of preparation: August 2023

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in Google Play or Apple App Store. Adverse events should also be reported to Bayer plc. Tel: 0118 206 3500, Fax: 0118 206 3703, E-mail: pvuk@bayer.com

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