LEVENORGESTREL + ETHINYLESTRADIOL

Indications/Uses

Contraception.

Dosage/Direction for Use

Adult: PO Monophasic combined OC: As tab containing levonogestrel 150-250 mcg and ethinylestradiol 30 mcg: 1 tab once daily. Triphasic combined OC: Levonorgestrel 50-125 mcg + ethinylestradiol 30-40 mcg: 1 tab once daily.

Contraindications

Pregnancy, undiagnosed vaginal bleeding, severe arterial disease (or family history of atherogenic lipid profile); liver adenoma; porphyria; after evacuation of hydatidiform mole; history of breast cancer; hepatic impairment; thrombophloebitis or thromboembolic disorders; breast carcinoma except in selected patients being treated for metastatic disease; oestrogen-dependent tumour; smoking ≥40 cigarettes daily; >50 yr; diabetes complications present; BMI >39 kg/m2; migraine with typical focal aura, lasting >72 hr despite treatment or migraine treated with ergot derivatives; BP >160 mmHg systolic and 100 mmHg diastolic; transient ischaemic attacks without headaches; SLE; gallstones; history of haemolytic uraemic syndrome, pruritis during pregnancy; cholestatic jaundice; chorea or deterioration of otosclerosis pemphigoid; breast feeding during 1st 6 mth after delivery.

Special Precautions

Sex-steroid dependent cancer; past ectopic pregnancy; malabsorption syndromes; functional ovarian cysts; active liver disease, recurrent cholestatic jaundice, history of jaundice in pregnancy; history of CV or renal impairment; DM; asthma; epilepsy; migraine; depression; lactation; conditions exacerbated by fluid retention; hypercalcaemia; CV and gall bladder diseases; lipid effects; familial defects of lipoprotein metabolism; patients at risk of venous thromboembolism, breast cancer, preexisting uterine leiomyomata and benign hepatic adenoma; family history of arterial disease in 1st degree relative <45 yr; BP > systolic 140 mmHg and diastolic 90 mmHg; >35 yr; BMI 30-39 kg/m2; migraine without focal aura, controlled with 5HT1; GI upset (vomiting and diarrhoea), missed pills and interaction with other drugs may require additional contraceptive precautions. Should be taken at same time each day.

Adverse Reactions

Menstrual irregularities; headache, dizziness; breast discomfort; gynaecomastia; depression; disturbance of appetite; wt changes; fluid retention; oedema; changes in libido; hair loss or hirsutism; GI disturbances (nausea and vomiting); genitourinary changes; haematologic disorders; endocrine and metabolic disorders; cholestatic jaundice; local skin reactions; chorea; contact lens intolerance; steeping of corneal curvature; pulmonary thromboembolism; carbohydrate and/or glucose intolerance; depression; chloasma; BP increase, liver impairment; reduced menstrual loss, 'spotting' in early cycles, absence of withdrawal bleeding; rarely photosensitivity; increased risk in breast cancer; elevation of plasma bound iodine, cortisol and thyroid binding, erythrocyte sedimentation may be accelerated; increases in plasma copper, iron and alkaline phosphatase; may affect serum triglyceride and lipoprotein levels; retinal vascular thrombosis.

Potentially Fatal: Hepatic tumours; increased risk of thromboembolism.

Drug Interactions

CYP3A4 inducers may decrease levels/effects eg aminoglutethimide, carbamazepine, nafcillin, nevirapine, atazanavir, nelfinavir, phenobarbital, phenytoin, lamotrigine, rifamycins, griseofulvin and ritonavir; ampicillin, tetracycline and other antibiotics may reduce efficacy; oestrogens may antagonise anticoagulant effect of coumarins; may inhibit metabolism of prednisolone and ciclosporin; may reduce clearance of alprazolam, chlordiazepoxide, diazepam; may increase clearance of lorazepam, oxazepam, temazepam.

CIMS Class

Oral Contraceptives

ATC Classification

G03AC03 - levonorgestrel ; Belongs to the class of progestogens. Used as systemic contraceptives.

G03AD01 - levonorgestrel ; Belongs to the class of emergency contraceptives. Used as systemic contraceptives.