NORTAS CR

COMPOSITION: Norethisterone acetate (controlled release) 10mg, DESCRIPTION: Norethisterone acetate is a synthetic, orally active progestin, is the acetic acid ester of norethisterone. THERAPEUTIC INDICATIONS: Nortas CR® is indicated for the treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer. It is not intended, recommended or approved to be used with concomitant estrogen therapy in postmenopausal women for endometrial protection. DOSAGE AND ADMINISTRATION: Abnormal uterine bleeding- One tablet, Nortas CR 10 mg given daily for 3-5 days to stop bleeding episode .About 3 to 7 days after completion of treatment, withdrawal bleeding will occur.(1st day of withdrawl bleeding = 1st day of the cycle). This is Followed by treatment for 21 days from day. 5 - 25 of the cycle or 16th to the 25th day of the cycle with 5 mg to 10 mg norethisterone tablet.Treatment for 21 days from day 5 - 25 of the cycle has been shown to be effective in reducing menstrual blood loss in menorrhagia.Therapy is given for 3-4 cycles to regularize menstrual bleeding. Secondary amenorrhoea. Nortas CR 10 mg is given daily for 5-10 days to produce secretory transformation of endometrium that has been adequately primed with either endogenous or exogenous estrogen.Within 3-7 days after discontinuing therapy, progestin withdrawal bleeding usually occurs. CONTRAINDICATIONS: Known or suspected pregnancy, Undiagnosed vaginal bleeding, Known, suspected or history of cancer of the breast, Active deep vein thrombosis, pulmonary embolism or history of these conditions, Active or recent (e.g., within the past year) arterial thromboembolic disease (e.g., stroke, myocardial infarction), Impaired liver function or liver disease, As a diagnostic test for pregnancy, Hypersensitivity to any of the drug components. WARNINGS: 1. Cardiovascular disorders Patients with risk factors for arterial vascular disease (e.g., hypertension, diabetes mellitus, tobacco use, hypercholesterolemia, and obesity) and/or venous thromboembolism (e.g., personal history or family history of VTE, obesity, and systemic lupus erythematosus) should be managed appropriately. 2. Visual abnormalities 3. Discontinue medication pending examination if there is a sudden