

REGESTRONE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for REGESTRONE [Norethindrone Acetate Tablets U.S.P]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Inhibits pituitary gonadotropin release, transforms proliferative to secretory endometrium, thickens cervical mucus. In carcinoma norethisterone may act by pituitary inhibition or by direct action on tumour deposits.

INDICATIONS: At low dose: Dysfunctional uterine bleeding, endometriosis, polymenorrhoea, menorrhagia, metropathia, haemorrhagia, postponement of menstruation and premenstrual syndrome. At High dose: Disseminated carcinoma of the breast.

DOSAGE AND ADMINISTRATION: 2.5 to 10 mg norethindrone acetate may be given daily for 5 to 10 days to produce secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen. Initial daily dosage of 5 mg norethindrone acetate for two weeks. Dosage should be increased by 2.5 mg per day every two weeks until 15 mg per day of norethindrone acetate is reached. Therapy may be held at this level for six to nine months or until annoying breakthrough bleeding demands temporary termination.

CONTRAINDICATION: Known or suspected pregnancy. There is no indication for norethindrone acetate in 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 & PRECAUTIONS: Discontinue medication pending examination if there is a sudden partial or complete loss of vision or if there is sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be discontinued. Because this drug may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, cardiac or renal dysfunctions, require careful observation. Impaired glucose metabolism. Reduced response to metyrapone test.

DRUG INTERACTIONS: No pharmacokinetic drug interaction studies investigating any drug-drug interactions with norethindrone acetate have been conducted.

ADVERSE REACTIONS: Breakthrough bleeding, Spotting, Change in menstrual flow, Amenorrhea, Edema, Changes in weight (decreases, increases), Changes in the cervical squamo-columnar junction and cervical secretions, Cholestatic jaundice, Rash (allergic) with and without pruritus, Melasma or chloasma, Clinical depression, Acne, Breast enlargement/tenderness, Headache/migraine, Urticaria, Abnormalities of liver tests (i.e., AST, ALT, Bilirubin), Decreased HDL cholesterol and increased LDL/HDL ratio, Mood swings, Nausea, Insomnia, Anaphylactic/anaphylactoid reactions, Thrombotic and thromboembolic events (e.g., deep vein thrombosis, pulmonary, embolism, retinal vascular thrombosis, cerebral thrombosis and embolism), Optic neuritis (which may lead to partial or complete loss of vision)

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/ REGESTRONE 5mg /November-20/01/ABPI

(Additional information is available on request)