

REGESTRONE CR 15

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

Abbreviated Prescribing information for **REGESTRONE CR 15** [Norethisterone Acetate
Controlled Release Tablets (15 mg)]

[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.

INDICATION: It is indicated to arrest bleeding in women with Heavy Menstrual Bleeding (HMB)/ Abnormal Uterine Bleeding (AUB) due to hormonal imbalance.

DOSAGE AND ADMINISTRATION: As directed by the physician. Oral Administration

CONTRAINDICATION: Hypersensitivity to the active substance or any of the excipients. Pregnancy. Previous idiopathic or current venous thromboembolism (deep vein thrombosis, pulmonary embolism). Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction). Disturbance of liver function. History during pregnancy of idiopathic jaundice. Severe pruritus or pemphigoid gestationis. Undiagnosed irregular vaginal bleeding. Porphyria.

WARNINGS & PRECAUTIONS: Not to be sold for pregnancy test and in suspected cases of pregnancy. Therapy should be discontinued if the following occur: Jaundice or deterioration in liver function, significant increase in blood pressure & new onset of migraine-type headache. Risk of venous thromboembolism (VTE).

DRUG INTERACTIONS: The metabolism of progestogens may be increased by concomitant administration of cytochrome P450 enzymes. These compounds include anticonvulsants (e.g., phenobarbital, carbamazepine etc.) and anti-infectives (e.g., rifampicin, tetracyclines, etc.). Special care should be taken when progestogens are administered with other drugs which also cause fluid retention, such as NSAIDs and vasodilators.

ADVERSE REACTIONS: Progestogens given alone at low doses have been associated with the following undesirable effects: breakthrough bleeding, spotting, amenorrhoea, abnormal uterine bleeding, depression, headache, dizziness, fatigue, insomnia, nervousness, hepatic adenoma, altered serum lipid and lipoprotein profiles, increased fasting glucose levels, adrenergic-like effects (e.g., fine hand tremors, sweating, cramps in calves at night), corticoid-like effects (e.g., Cushingoid syndrome), cerebral and myocardial infarction, congestive heart failure, increased blood pressure, palpitations, pulmonary embolism, tachycardia, thrombophlebitis, acne, hirsutism, alopecia, pruritis, rash, urticaria, hypersensitivity reactions, bloating, weight gain, pyrexia, change in appetite, change in libido, hypercalcaemia, malaise.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/REGESTRONE CR 15 mg/Jul-20/01/ABPI

(Additional information is available on request)