

## REGESTERONE CR

**For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory**

Abbreviated Prescribing information for **REGESTERONE CR** [Norethisterone Acetate CR Tablets 10 mg] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** Norethisterone has typical effects of a progestogen and converts the endometrium from the proliferative to the secretory phase. It delays onset of periods and controls abnormal uterine bleeding.

**INDICATION:** Dysfunctional bleeding, Slight bleeding during tablet-taking, Missing arrest of haemorrhage, heavy breakthrough bleeding, Secondary amenorrhoea not due to pregnancy.

**DOSAGE AND ADMINISTRATION:** Starting on the first day of menstruation, one pill every day without a break in medication for as long as contraception is required. Additional contraceptive precautions (such as a condom) should be taken for the first 7 days of the first pack. Pills should be taken at the same time each day.

**CONTRAINDICATION:** It is contraindicated in breast, genital or hormone dependent cancer, liver tumours, Dubin-Johnson or Rotor syndrome, active liver disease, history during pregnancy of idiopathic jaundice or severe pruritus, disorders of lipid metabolism, undiagnosed abnormal vaginal bleeding, known or suspected pregnancy, existence, or history of thrombophlebitis, thromboembolic disorders, cerebral vascular disease, myocardial infarction, angina, or coronary artery disease be described as a contraindication to Regesterone as it is to oestrogen containing oral contraceptives.

**WARNINGS & PRECAUTIONS:** Malignant hepatic tumors have been reported on rare occasions in long-term users. A hepatic tumour should be considered in the differential diagnosis when upper abdominal pain, enlarged liver or signs of intra-abdominal hemorrhage occur. Patients should be kept under regular surveillance, in view of the possibility of development of conditions such as thrombo-embolism. Regesterone should be discontinued at least 4 weeks before elective surgery or during periods of prolonged immobilisation. Regesterone may cause fluid retention. There is a slightly increased relative risk of having breast cancer. **WARNING: Not to be sold for pregnancy test and in suspected case of pregnancy.**

**DRUG INTERACTIONS:** It may interact with Hypericum perforatum, certain sedatives, antibiotics, and antiepileptics, prednisone, prednisolone, cloprednol and possibly other corticosteroids.

**ADVERSE REACTIONS:** Cycle irregularity during the first few months of therapy, spotting or breakthrough bleeding, amenorrhoea, breast discomfort, gastrointestinal symptoms, rash, headaches, migraine, depression, fatigue, nervousness, disturbance of appetite and changes in weight and libido, and Hypertension.

**MARKETED BY:**



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**IN/ REGESTERONE CT 10mg/AUG-17/01/PI**

(Additional information is available on request)