

ENDOBREAK

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

Abbreviated Prescribing information for ENDOBREAK (Dienogest Tablets 2 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Dienogest is a novel nortestosterone derivative with no androgenic but rather an antiandrogenic activity of approximately one third that of cyproterone acetate. Dienogest binds to the progesterone receptor of the human uterus with only 10% of the relative affinity of progesterone.

INDICATIONS: For the management of Pelvic pain associated with Endometriosis.

DOSAGE AND ADMINISTRATION: As directed by physician. Dose should be taken orally

CONTRAINDICATION: ENDOBREAK should not be used in women with known or suspected pregnancy, Lactation, Active venous thromboembolic disorder, Arterial and cardiovascular disease, past or present (e.g. myocardial infarction, cerebrovascular accident, ischemic heart disease), Diabetes mellitus with vascular involvement, Presence or history of severe hepatic disease as long as liver function values have not returned to normal, Presence or history of liver tumors (benign or malignant), Known or suspected sex hormone-dependent malignancies, Undiagnosed abnormal vaginal bleeding, Any ocular lesion arising from ophthalmic vascular disease, such as partial or complete, loss of vision or defect in visual fields, Current or history of migraine with focal aura, Hypersensitivity to dienogest or to any ingredient in the formulation or component of the container.

WARNINGS & PRECAUTIONS: During treatment, patients are advised to use non-hormonal methods of contraception (e.g. barrier method) if contraception is required. Hormonal methods of contraception should not be used in combination with ENDOBREAK. As ENDOBREAK is a progestin-only therapy, it can be assumed that special warnings and special precautions for use of other progestin-only therapies are valid for the use of ENDOBREAK although not all of the warnings and precautions are based on respective findings in the clinical studies with ENDOBREAK.

DRUG INTERACTIONS: Progestogens, including dienogest are metabolised mainly by the cytochrome P450 3A4 system (CYP3A4) located both in the intestinal mucosa and in the liver. Therefore, inducers or inhibitors of CYP3A4 may affect the progestogen drug metabolism. Substances increasing the clearance of sex hormones (diminished efficacy by enzyme induction) e.g. Phenytoin, barbiturates, primidone, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin and products containing St. John's Wort. Substances with variable effects on the clearance of sex hormones, (e.g. nevirapine): When co-administered with sex hormones, many HIV/HCV protease inhibitors (e.g. ritonavir, Saquinavir, indinavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors can increase or decrease plasma concentrations of the progestogen.

ADVERSE REACTIONS: Most common side effects during the first months after the start of ENDOBREAK are changed in menstrual bleeding pattern (i.e.: spotting, irregular bleeding, or periods may stop completely). Common side effects: Anaemia, weight gain, depressed mood, problems sleeping, nervousness, or loss of interest in sex, headache or migraine, nausea or abdominal pain, acne or hair loss, breast discomfort, ovarian cyst, uterine/vaginal bleeding including spotting, generalized weakness, irritability, Uncommon side effects, increase in appetite, anxiety, depression, changed mood, or mood swings, disturbed attention, dry eyes, ringing in the ears, palpitation.

MARKETED BY:



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(Additional information is available on request)