Venesa

Tablet

Dienogest EP

Composition
Each tablet contains Dienogest EP 2 mg.

Pharmacology
Mode of action : Dienogest reduces the endogenous production of Estradiol and thereby suppresses the trophic effects of Estradiol on both the eutopic and ectopic endometrium. When given continuously, dienogest leads to a hyperprogestogenic and moderately hypo estrogenic endocrine environment causing initial decidualization of endometrial tissue. Additional direct antiproliferative, immunologic and antiangiogenic effects seem to contribute to the inhibitory action of Dienogest on cell proliferation and to the reduction of pelvic pain associated with endometriosis.
Absorption : Dienogest is rapidly and almost completely absorbed following oral Administration Peak serum concentrations of 47 ng/ml are reached at about 1.5 hours after single ingestion of 2 mg. Bioavailability is about 91%.
Metabolism: Dienogest is completely metabolized by the liver with the formation of mostly inactive metabolities. CYP3A4 is the major enzyme involved in the metabolism of Dienogest.
Excretion : The half-life of urinary metabolites excretion is 14 hours. Following oral administration, most of the drug is excreted in the urine within the first 24 hours.

Indications
Treatment of Endometriosis.

Dosage and Administration
Route of administration : Oral.
One tablet should be swallowed daily without any break, preferably at the same time, with some liquid as needed. Venesa can be taken with or without food. Tablets must be taken continuously without regard to vaginal bleeding.
Missed dose : In the event of one or more missed tablets, the woman should take one tablet only, as soon as she remembers, and should then continue the next day at her usual time. A tablet not absorbed due to vomiting or diarrhea should likewise be replaced by one tablet.

Contraindications
Dienogest should not be used in women with any of the conditions listed below : Known or suspected pregnancy, lactation, Active venous thromboembolic disorder, Arterial and Cardiovascular 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 or vision or defect in visual fields, current or history of migraine with focal aure, hypersensitivity to Dienogest or to any ingredient in the formulation.

Warning & Precautions
Before initiating treatment with Dienogest, pregnancy must be excluded; during treatment, Hormonal methods of contraception should not be used and patients are advised to use non-hormonal methods of contraception if contraception is required. It can be assumed that special warnings and special precautions for use of other progestin only therapies are valid for the use of Dienogest, although not all of the warnings and precautions are based on respective finding in the clinical studies with Dienogest. Women should be counselled not to smoke.

Side-Effects
The most frequently reported adverse drug reactions during treatment with Dienogest in clinical trials were headache, breast discomfort, depressed mood, and acne. The continuous administration of progestins in general leads to endometrial regression, with irregular endometrial breakthrough bleeding, particularly during the first weeks or use. Therefore changes in bleeding patern such as spotting, irregular bleeding, or amenorrhea occurred during treatment with Dienogest.

Use in pregnancy & Lactation
Pregnancy : The administration of Dienogest during pregnancy is contraindicated. If pregnancy occurs during treatment with Dienogest, further intake must be stopped.
Lactation: Dienogest is contraindicated during lactation. Though Dienogest is excreted in rat milk, it is unknown if it is excreted in human milk.

Use in Children & Adolescents
Dienogest is not intended for use prior to menarche.

Geriatric Use
There is no relevant indication for use of Dienogest in the Geriatric population.

Patients with hepatic impairment
Dienogest is contraindicated in patients with present or past severe hepatic disease.

Patient with renal impairment
There are no data suggesting the need for a dosage adjustment in patients with renal impairment.

Drug Interactions
Progestogens including Dienogest are metabolized mainly by the CYP3A4 system. Therefore, inducers or inhibitors of CYP3A4 may affect the progestogen drug metabolism. Known CyP3A4 inhibitors like azole antifungal (e.g. Ketoconazole, Itraconazole, Fluconazole), Cimetidine, Verapamil. Macrolides (e.g. Erythromycin, Clarithromycin and Roxithromycin) can result in decreased clearance of sex hormones, inducers (e.g. phenytoin, barbiturates, primidone, carbamazepine etc) can result in increased clearance of sex hormones.

Overdose
Acute toxicity studies performed with Dienogest did not indicate a risk of acute adverse effects in case of inadvertent intake of a multiple of the daily therapeutic dose. There is no specific antidote. A daily intake of 20-30 mg Dienogest (10 to 15 times higher dose than in Venesa) over 24 weeks of use was very well tolerated.

Storage
Store below 30°C & in dry place, protected from light.
Keep all medicine out of the reach of children.

Packing
Each box contains 1 X 10 tablets in blister pack.

*** Further information is available on request.**

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness