Dinogest®

Dienogest

Tablet

Description

Dinogest® is the preparation of Dienogest which belongs to the class of medications called progestins. Progestins reduce the effects of estrogen on tissues such as the endometrium (lining of the uterus) and the breast. By reducing the growth effect of estrogen on the endometrium, Dienogest helps to reduce the pelvic pain experienced by women with endometriosis.

Indications

Treatment of endometriosis.

Dosage and Administration

Tablet-taking can be started on any day of the menstrual cycle.

The dosage of Dinogest® is 1 tablet daily without any break, taken preferably at the same time each day with some liquid as needed. Tablet must be taken continuously without regard to vaginal bleeding. When a pack is finished, the next one should be started without interruption.

In the event of missed tablet(s), the woman should take 1 tablet only, as soon as she remembers, and should then continue the next day to take the tablet at her usual time. A tablet not absorbed due to vomiting or diarrhea should likewise be replaced by 1 tablet.

Overdosage

Acute toxicity studies performed with Dinogest® 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. Dienogest 20-30 mg/day (10-15 times higher dose than in Dinogest®) over 24 weeks of use were very well tolerated.

Contraindications

Hypersensitivity to dienogest or to any of the excipients of Dinogest®. Dienogest should not be used in the presence of any of the conditions such as, Active venous thromboembolic disorder; arterial and cardiovascular disease, (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 and undiagnosed vaginal bleeding.

Special Precautions

Before starting Dinogest® treatment, pregnancy must be excluded. During treatment, patients are advised to use nonhormonal methods of contraception (e.g, barrier method) if contraception is required.

As Dinogest® is a progestogen-only preparation, it can be assumed that special warnings and special precautions for use of other progestogen-only preparations are also valid for the use of Dinogest®.

Changes in Bleeding Pattern: Dinogest® treatment affects the menstrual bleeding pattern in the majority of women.

Hepatic Impairment: Dienogest is contraindicated in patients with present or past severe hepatic disease.

Impairment of Fertility: Based on available data, ovulation is inhibited in the majority of patients during treatment with Dinogest®. However, Dinogest® is not a contraceptive.

If contraception is required, a nonhormonal method should be used.

Use in Pregnancy: There are limited data from the use of dienogest in pregnant women. Animal studies and data from women exposed to dienogest during pregnancy reveal no special risks on pregnancy, embryonic/fetal development, birth or development after birth for humans. However, Dinogest® should not be administered to pregnant women because there is no need to treat endometriosis during pregnancy.

Use in Lactation: Treatment with Dinogest® during lactation is not recommended. Physiochemical properties and animal data indicate excretion of dienogest in breast milk. A decision must be made whether to discontinue breastfeeding or to abstain from Dinogest® therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

Use in Children: Dinogest® is not indicated in children prior to menarche. The safety and efficacy of Dinogest® in adolescents (menarche to 18 years) has not yet been established.

Use in the Elderly: There is no relevant indication for the use of Dinogest® in the geriatric population.

Adverse Reactions

Undesirable effects are more common during the 1st months after start of intake of Dienogest, and subside with duration of treatment. The following undesirable effects have been reported in users of Dienogest.

The most frequently reported undesirable effects during treatment that were considered at least possibly related to Dienogest were headache (9%), breast discomfort (5.4%), depressed mood (5.1%) and acne (5.1%).

Nervous System Disorders: Headache, migraine.

Cardiac Disorders: Uncommon: Unspecified circulatory system disorder, palpitations.

Vascular Disorders: Uncommon: Hypotension.

Gastrointestinal Disorders: Common: Nausea, abdominal pain, flatulence.

Metabolism and nutrition disorders: Weight increase (3.6%)

Psychiatric Disorders: Depressed mood, irritability, nervousness, altered mood.

Drug Drug Interactions

Progestogens including Dienogest are metabolized mainly by the cytochrome P450 3A4 system . Therefore, inducers or inhibitors of CYP3A4 may affect the progestogen drug metabolism. Known CYP3A4 inhibitors like azole antifungals (e.g, ketoconazole, itraconazole, fluconazole), cimetidine, verapamil, macrolides (e.g, erythromycin, clarithromycin and roxithromycin), diltiazem, protease inhibitors (e.g, ritonavir, saquinavir, indinavir, nelfinavir), antidepressants (e.g, nefazodone, fluvoxamine, fluoxetine) may increase plasma levels of progestogens and result in adverse reactions.

Pharmaceutical Precaution

Keep in a cool and dry place. Protect from light. Keep out of the reach of children.

Commercial Pack

Dinogest® Tablet: Box containing 10 tablets in 1X10's blister strips. Each tablet contains Dienogest INN 2 mg.

BEXIMCO PHARMA

Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH BL 0006 201016

Manufactured by Beximco Pharmaceuticals Ltd. at Nuvista Pharma Limited, Tongi- Gazipur

105 mm x 160 mm FS

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