Endosis™

Dienogest BP Tablet

COMPOSITION
Each tablet contains Dienogest BP 2 mg.

DESCRIPTION
Endosis™ is the preparation of Dienogest which belongs to the class of medications called progestins. Progestins reduce the effects of estrogen on tissue 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.

INDICATION
Treatment of endometriosis.

DOSAGE AND ADMINISTRATION
Tablet-taking can be started on any day of the menstrual cycle. The dosage of **Endosis**™ 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 any 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. If a tablet not absorbed due to vomiting or diarrhea should likewise be replaced by 1 tablet. Any hormonal contraception needs to be stopped prior to initiation of treatment with **Endosis**™. If required non-hormonal method of contraception should be used.

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. Dienogest 20-30 mg/day (10-15 times higher dose) over 24 weeks of use were very well tolerated.

CONTRAINDICATIONS
Hypersensitivity to Dienogest. 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 liver tumors (benign or malignant); known or suspected sex hormone-dependent malignancies and undiagnosed vaginal bleeding.

SPECIAL PRECAUTIONS
Before starting Dienogest treatment, pregnancy must be excluded. During treatment, patients are advised to use nonhormonal methods of contraception if contraception is required. As Dienogest 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 Dienogest.

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

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, Dienogest should not be administered to pregnant women because there is no need to treat endometriosis during pregnancy.

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

Use in children:
Dienogest is not indicated in children prior to menarche. The safety and efficacy of dienogest in adolescents has not yet been established.

Use in the elderly:
There is no relevant indication for the use of Dienogest 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 most frequently reported undesirable effects during treatment that were considered at least possibly related to Dienogest were headache, breast discomfort, depressed mood and acne.
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.
Psychiatric Disorders: Depressed mood, irritability, nervousness, altered mood.

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
Store at or below 30 ˚C temperature. Keep away from light and wet place. Keep out of reach of children.

COMMERCIAL PACK
Endosis™ **Tablet:** Each box containing one strip of 10 tablets each. Each tablet contains Dienogest BP 2 mg.

SK+F
Manufactured for
ESKAYEF PHARMACEUTICALS LTD.
By **POPULAR PHARMACEUTICALS LTD.**
TONGI, GAZIPUR, BANGLADESH
TM TRADEMARK
PM07126 V01