CHATEAL®
(Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15/0.03 mg)

PRODUCT INFORMATION SHEET

GENERIC NAME
Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.15/0.03 mg

AB-RATED REFERENCE DRUG
Nordette®

COMPARES TO
Levora®, Portia®, Altavera®, Marlissa®, Kurvelo®

DRUG INFORMATION CLASSIFICATION NUMBER
68:12.00, oral

ANDA NUMBER
091663

DATE OF FDA APPROVAL
12/21/2012

INGREDIENTS
21 white to off-white active tablets, each containing 0.15 mg of levonorgestrel, and 0.03 mg of ethinyl estradiol with the inactive ingredients Lactose Monohydrate, Polacrilin Potassium, and Magnesium Stearate. The 7 green inert tablets include the inactive ingredients Lactose Monohydrate, Polacrilin Potassium, Magnesium Stearate, Yellow Oxide of Iron, and FD&C Blue No.1 Aluminum Lake.

STORAGE INFORMATION
Store at 20°–25°C (68°–77°F) [See USP Controlled Room Temperature].

TABLET DESCRIPTION
Active: White to off-white, uncoated, unscored, round, tablets debossed with 209 on one side. Inactive: Green, round, uncoated, unscored, tablets debossed with 274 on one side.

ADDITIONAL INFORMATION
To report SUSPECTED ADVERSE REACTIONS contact Afaxys at 1-855-888-2467.

For product quality issues or medical information contact Afaxys at 1-855-888-2467.

IMPORTANT SAFETY INFORMATION

WARNINGS
The use of oral contraceptives is associated with increased risk of several serious conditions including venous and arterial thromboembolic events (such as myocardial infarction, thromboembolism, stroke), hepatic neoplasia, gallbladder disease, and hypertension. The risk of serious morbidity and mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of underlying risk factors such as certain inherited or acquired thrombophilias, hypertension, obesity, and diabetes.

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with the extent of smoking (in epidemiologic studies, 15 or more cigarettes per day was associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

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Please see reverse side for Important Safety Information.
For further Important Safety Information see full Prescribing Information including Indications, Contraindications, Warnings, Precautions, and Adverse Reactions.

Ordering and Contact Information:
Go to afaxys.com/pharma to find your authorized distributor and to obtain pricing.

PACKAGING

<table>
<thead>
<tr>
<th>Description</th>
<th>NDC</th>
<th>Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monocarton containing 28-tablet Blister Pack</td>
<td>50102-130-01</td>
<td>105 mm x 20 mm x 75 mm</td>
</tr>
<tr>
<td>Clinic Pack containing 48 Monocartons</td>
<td>50102-130-48</td>
<td>255 mm x 306 mm x 109 mm</td>
</tr>
<tr>
<td>Shipper containing 3 Clinic Packs</td>
<td>50102-130-90</td>
<td>330 mm x 280 mm x 360 mm</td>
</tr>
</tbody>
</table>
Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

INDICATIONS AND USAGE
Oral contraceptives are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception.

CONTRAINDICATIONS
Combination oral contraceptives should not be used in women with any of the following conditions:

- Thrombophlebitis or thromboembolic disorders.
- A past history of deep-vein thrombophlebitis or thromboembolic disorders.
- Cerebral-vascular or coronary artery disease.
- Thrombogenic valvulopathies.
- Thrombogenic rhythm disorders.
- Uncontrolled hypertension.
- Diabetes with vascular involvement.
- Known or suspected carcinoma of the breast.
- Carcinoma of the endometrium in other known or suspected estrogen-dependent neoplasia.
- Undiagnosed abnormal genital bleeding.
- Cholestatic jaundice of pregnancy or jaundice with prior pill use.
- Hepatic adenomas or carcinomas, or active liver disease, as long as liver function has not returned to normal.
- Known or suspected pregnancy.
- Hypersensitivity to any component of CHATEAL (levonorgestrel and ethinyl estradiol tablets, USP).

WARNINGS
Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with the extent of smoking (in epidemiologic studies, 15 or more cigarettes per day was associated with a significantly increased risk) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as myocardial infarction, thromboembolism, and stroke), hepatic neoplasia, gallbladder disease, and hypertension, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as certain inherited or acquired thrombophilias, hypertension, hyperlipidemias, obesity, and diabetes.

Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks:

1. THROMBOEMBOLIC DISORDERS AND OTHER VASCULAR PROBLEMS
   a. Myocardial Infarction
   An increased risk of myocardial infarction has been attributed to oral contraceptive use. This risk is primarily in smokers or women with other underlying risk factors for coronary artery disease such as hypertension, hypercholesterolemia, morbid obesity, and diabetes.
   The relative risk of heart attack for current oral contraceptive users has been estimated to be two to six. The risk is very low under the age of 30. Smoking in combination with oral contraceptive use has been shown to contribute substantially to the incidence of myocardial infarctions in women in their mid-thirties or older with smoking accounting for the majority of excess cases. Mortality rates associated with cardiovascular disease have been shown to increase substantially in smokers over the age of 35 and nonsmokers over the age of 40 among women who use oral contraceptives. Oral contraceptives may compound the effects of well-known risk factors, such as hypertension, diabetes, hyperlipidemias, age, and obesity.
   Oral contraceptives have been shown to increase blood pressure among oral contraceptive users, and should be used with caution in women with cardiovascular risk factors.
   b. Thromboembolism
   An increased risk of venous thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. The approximate incidence of deep-vein thrombosis and pulmonary embolism in users of low-dose (<50 mcg ethinyl estradiol) combination oral contraceptives is up to 4 per 10,000 women-years compared to 0.5 to 1 per 10,000 women-years for nonusers. However, the incidence is substantially less than that associated with oral oophorectomy (6 per 10,000 women-years). The risk of thromboembolic disease due to oral contraceptives is not related to length of use and disappears after pill use is stopped. If feasible, oral contraceptives should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than four to six weeks after delivery in women who elect not to breast-feed, or a midtrimester pregnancy termination.
   c. Cerebrovascular Diseases
   Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (>35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both thrombotic and hemorrhagic strokes, while smoking interacted to increase the risk for hemorrhagic strokes.
   2. ESTIMATES OF MORTALITY FROM CONTRACEPTIVE USE
   Each method of contraception has its specific benefits and risks. Please see full Prescribing Information for comparative table of mortality risks from contraceptive use.
   3. CARCINOMA OF THE REPRODUCTIVE ORGANS
   A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using combination oral contraceptives compared to never-users. The increased risk gradually disappears during the course of the 10 years after cessation of combination oral contraceptive use. These studies do not provide evidence for causation. The observed pattern of increased risk of breast cancer diagnosis may be due to earlier detection of breast cancer in combination oral contraceptive users, the biological effects of combination oral contraceptives, or a combination of both. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent combination oral contraceptive users is small in relation to the lifetime risk of breast cancer. Breast cancers diagnosed in ever-users tend to be less advanced clinically than the cancers diagnosed in never-users.
   Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia or invasive cervical cancer in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.
   In spite of many studies of the relationship between oral contraceptive use and breast and cervical cancers, a cause-and-effect relationship has not been established.

4. HEPATIC NEOPLASIA
   Benign hepatic adenomas are associated with oral contraceptive use, although the incidence of benign tumors is rare in the United States. Rupture of rare, benign, hepatic adenomas may cause death through intra-abdominal hemorrhage. Studies from Britain have shown an increased risk of developing hepatocellular carcinoma in long-term (>8 years) oral contraceptive users. However, these cancers are extremely rare in the United States, and the attributable risk (the excess incidence) of liver cancers in oral contraceptive users is less than one per million users.
   Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia or invasive cervical cancer in some populations of women. However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.
   In spite of many studies of the relationship between oral contraceptive use and breast and cervical cancers, a cause-and-effect relationship has not been established.
   5. OCULAR LESIONS
   The onset or exacerbation of migraine or development of headache with a new pattern that is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause.

11. BLEEDING IRREGULARITIES
   Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. The type and dose of progestogen may be important. Nonhormonal causes should be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy in the event of breakthrough bleeding, as is the case of any abnormal vaginal bleeding. If pathology has been excluded, time or a change to another formulation may solve the problem. In the event of amenorrhea, pregnancy should be ruled out.
   Some women may encounter post-pill amenorrhea or oligomenorrhea (possibly with an ovulation), especially when such a condition was precipitant.

OVERDOSAGE
Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdose may cause nausea, and withdrawal bleeding may occur in females.

DOSAGE AND ADMINISTRATION
To achieve maximum contraceptive effectiveness, CHATEAL must be taken exactly as directed and at intervals not more than 24 hours apart.