Aubra™
(Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.1 mg/0.02 mg)

PRODUCT INFORMATION SHEET

GENERIC NAME
Levonorgestrel and Ethinyl Estradiol Tablets, USP 0.1 mg/0.02 mg

REFERENCE DRUG
Lutera®

OTHER GENERIC VERSIONS TO REFERENCE DRUG
Aviane®, Lessina®, Levilite®, Orsytia®, Sronyx®, Alesse®, and Falmina®

DRUG INFORMATION CLASSIFICATION NUMBER
68:12.00, oral

ANDA NUMBER
200245

DATE OF FDA APPROVAL
10/9/13

INGREDIENTS
Each active, light yellow tablet (21) contains 0.1 mg of levonorgestrel and 0.02 mg of ethinyl estradiol. The inactive ingredients present are croscarmellose sodium, ferric oxide of iron (yellow), ferric oxide of iron (red), lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K-25, and sodium lauryl sulfate. Each inactive, brown tablet (7) contains the following inactive ingredients: croscarmellose sodium, ferric oxide of iron (brown), lactose monohydrate, magnesium stearate, microcrystalline cellulose, and povidone K-25.

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

TABLET DESCRIPTION
Active: Light yellow colored, uncoated, round, unscored, flat tablets debossed with “201” on one side and blank on the other side. Inert: Brown colored, uncoated, round, unscored, flat tablets debossed with “271” on one side and blank on the other side.

ADDITIONAL INFORMATION
To report SUSPECTED ADVERSE REACTIONS contact the Afaxys Health and Safety team at 1-855-888-2467 or report to the FDA Medwatch Program at 1-800-FDA-1088 or online at www.fda.gov/medwatch. For product quality issues or medical information contact Afaxys at 1-855-888-2467.

Please see reverse side for IMPORTANT SAFETY INFORMATION. Please see full Prescribing Information for Indications, Contraindications, Warnings, Precautions, Adverse Reactions, and Patient Information.

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>
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</thead>
<tbody>
<tr>
<td>Monocarton containing 28-tablet Blister Pack</td>
<td>50102-120-01</td>
<td>105 mm x 18 mm x 74 mm</td>
</tr>
<tr>
<td>Clinic Pack containing 48 Monocartons</td>
<td>50102-120-48</td>
<td>250 mm x 302 mm x 109 mm</td>
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<tr>
<td>Shipper containing 3 Clinic Packs</td>
<td>50102-120-90</td>
<td>325 mm x 270 mm x 360 mm</td>
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Patients should be counseled that oral contraceptives do not protect against transmission of HIV (AIDS) and other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

INDICATIONS AND USAGE
Combination 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:

1. Thrombophlebitis or thromboembolic disorders
2. A history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Valvular heart disease with thrombogenic complications
5. Thrombogenic rhythm disorders
6. Hereditary or acquired thrombophilias
7. Major surgery with prolonged immobilization
8. Diabetes with vascular involvement
9. Headaches with focal neurological symptoms
10. Uncontrolled hypertension
11. Known or suspected carcinoma of the breast or personal history of breast cancer
12. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
13. Undiagnosed abnormal genital bleeding
14. Cholestatic jaundice of pregnancy or jaundice with prior pill use
15. Hepatic adenomas or carcinomas, or active liver disease
16. Known or suspected pregnancy
17. Hypersensitivity to any of the components of levonorgestrel and ethinyl estradiol tablets

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.

RISKS
The use of oral contraceptives is associated with increased risks 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, hyperlipidemia, obesity, diabetes, and surgery or trauma with increased risk of thrombosis. Practitioners prescribing oral contraceptives should be familiar with information relating to these risks.

Risk information described in the full Prescribing Information includes:
1. Thromboembolic Disorders and Other Vascular Problems
2. Estimates of Mortality from Contraceptive Use
3. Carcinoma of the Reproductive Organs and Breasts
4. Hepatic Neoplasia
5. Ocular Lesions
6. Oral Contraceptive Use Before or During Early Pregnancy
7. Gallbladder Disease
8. Carbohydrate and Lipid Metabolic Effects
9. Elevated Blood Pressure
10. Headache
11. Bleeding Irregularities
12. Ectopic Pregnancy

DOSAGE AND ADMINISTRATION
To achieve maximum contraceptive effectiveness, Aubra (levonorgestrel and ethinyl estradiol tablets) must be taken exactly as directed and at intervals not exceeding 24 hours.