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Aubra®

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

AUBRA® IS AN AB-RATED GENERIC ORAL CONTRACEPTIVE REFERENCE DRUG
Lutera®

COMPARES TO

Aviane®, Orsythia®, Sronyx® and Falmina®



A progestin-estrogen combination oral contraceptive

Single-phase continuous administration regimen

- 21 white to off-white tablets of levonorgestrel and ethinyl estradiol
- 7 brown non-hormone containing tablets to help ease administration

28-day tablet blister pack makes dosing easy and convenient

ORDERING INFORMATION

Order from your local drug distributor today

PACKING

Description	NDC	Dimensions
Monocarton Containing 28-tablet Blister Pack	50102-120-01	105 mm x 18 mm x 74 mm
Box Containing 48 Monocartons	50102-120-48	250 mm x 302 mm x 109 mm

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

To report SUSPECTED ADVERSE REACTIONS, call 1-855-888-2467 or report via the FDA Medwatch Program at www.fda.gov/medwatch or 1-800-FDA-1088.

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Important Safety Information

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:

- Thrombophlebitis or thromboembolic disorders
- A history of deep-vein thrombophlebitis or thromboembolic disorders
- Cerebrovascular or coronary artery disease (current or past history)
- Valvular heart disease with thrombogenic complications
- Thrombogenic rhythm disorders
- Hereditary or acquired thrombophilias
- Major surgery with prolonged immobilization
- Diabetes with vascular involvement
- Headaches with focal neurological symptoms
- Uncontrolled hypertension
- Known or suspected carcinoma of the breast or personal history of breast cancer
- Carcinoma of the endometrium or 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
- Known or suspected pregnancy
- 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, hyperlipidemias, 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.

Please see accompanying full Prescribing Information or online at afaxys.com.

