

Chateal[®]

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

CHATEAL[®] IS AN AB-RATED GENERIC ORAL CONTRACEPTIVE

REFERENCE DRUG

Levora[®]

COMPARES TO

Portia[®], Altavera[®], Marlissa[®] and Kurvelo[®]



A progestin-estrogen combination oral contraceptive

Single-phase continuous administration regimen

- 21 white to off-white tablets of levonorgestrel and ethinyl estradiol
- 7 green 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
Carton Containing 3 Packages	50102-130-03	156 mm x 89 mm x 61 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.

Please see Important Safety Information below.

Chateal®

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

Important Safety Information

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 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, 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)
- Are receiving Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations

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. Use in women receiving Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations
6. Ocular Lesions
7. Oral Contraceptive Use Before or During Early Pregnancy
8. Gallbladder Disease
9. Carbohydrate and Lipid Metabolic Effects
10. Elevated Blood Pressure
11. Headache
12. Bleeding Irregularities

ADVERSE REACTIONS

The most serious reactions are discussed in detail in the full product labeling and include serious cardiovascular events and smoking, vascular events and liver disease. Commonly reported adverse reactions include irregular uterine bleeding, nausea, breast tenderness and headache.

DOSAGE AND ADMINISTRATION

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

For full Prescribing Information, [click here](#).