Balcoltra®

(levonorgestrel and ethinyl estradiol tablets, USP, and ferrous bisglycinate tablets)
0.1mg/0.02mg and 36.5mg

# A Daily Dose of Balanced Control

## Balcoltra® offers a balance of high efficacy and low dose[1]

**Balcoltra is the only branded combination oral contraceptive (COC) with levonorgestrel and 21/7 dosing[2]**

- **Low-dose levonorgestrel/ethinyl estradiol COC[1]**
- **Familiar 21/7 dosing[1]**
- **Cycle control with 4% breakthrough bleeding[1]**
- **Approximately 1 unintended pregnancy per 100 woman-years[1]**

### Indications and Usage

Balcoltra is a progestin/estrogen combination oral contraceptive (COC) indicated for use by females of reproductive potential to prevent pregnancy.

## IMPORTANT SAFETY INFORMATION

**WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS**

**Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptive (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs are contraindicated in women who are over 35 years of age and smoke.**

### Contraindications

Balcoltra is contraindicated in women with a high risk of arterial or venous thrombotic diseases, liver tumors (benign or malignant) or liver disease, undiagnosed abnormal uterine bleeding, during pregnancy, with breast cancer or other estrogen- or progestin-sensitive cancer (now or in the past), hypersensitivity to any of the components, or in women who are currently taking Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir (with or without dasabuvir).

**Please see Important Safety Information throughout and accompanying Prescribing Information, including BOXED WARNING.**


Not an actual patient.

Avion PHARMACEUTICALS
1-888-612-8466
Alpharetta, GA 30005

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## Effective Pregnancy Prevention

A clinical trial with levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg tablets demonstrated a rate of approximately 1 pregnancy per 100 woman-years.[1]

**1477** women **17-49** **5** pregnancies reported[1]

**In a clinical study of a COC containing 0.1 mg levonorgestrel and 0.02 mg ethinyl estradiol:**

**Light Bleeding**

The mean intensity of withdrawal bleeding was **light**[3,†]

**4.7 Days**

The mean duration of withdrawal bleeding was **4.7 days**[3,†]

**4%**

**4% of patients** had period-like bleeding outside of their scheduled periods[1]

*†Outpatient multicenter, open-label trial with a single treatment group. A total of 1708 healthy women aged 17 to 49 years were enrolled in the study, providing 27,011 cycles of exposure. Study subjects participated for approximately 36 cycles, until they withdrew or were withdrawn, or until the study was terminated.[3]*


**Eligible patients pay only $21 per fill for Balcoltra® with our co-pay savings card.***

**Most eligible patients will pay no more than $21 per co-pay. Present this coupon with your prescription to your participating pharmacy. For each Balcoltra prescription, pay the first $21 of your out-of-pocket expense and Avion will cover up to $100 of your remaining expense. You could have additional responsibility depending on your insurance plan or remaining expense. This offer is good for 21 uses. Cardholders with questions, please call 1-877-838-3846 (8:30 AM-5:30 PM ET, Monday-Friday).*

## IMPORTANT SAFETY INFORMATION (cont.)

### Warnings and Precautions

- Discontinue Balcoltra if an arterial thrombotic event or venous thromboembolic event (VTE) occurs, and at least 4 weeks before and through 2 weeks after major surgery or other surgeries known to have an elevated risk of VTE as well as during prolonged immobilization. Balcoltra should not be started any earlier than 4 weeks after delivery, in women who are not breastfeeding. The use of COCs increases the risk of VTE. The risk of VTE is highest during the first year of use of COCs and when restarting hormonal contraception after a break of 4 weeks or longer. Use of COCs also increases the risk of arterial thromboses such as strokes and myocardial infarctions. Use COCs with caution in women with cardiovascular disease risk factors.
- If jaundice occurs, treatment should be discontinued.
- Balcoltra should not be prescribed for women with uncontrolled hypertension or hypertension with vascular disease. An increase in blood pressure has been reported in women taking COCs, and this increase is more likely in older women with extended duration of use. If Balcoltra is used in women with well-controlled hypertension, monitor blood pressure and stop treatment if blood pressure rises significantly.
- Women who are prediabetic or diabetic should be monitored while using Balcoltra. Alternate contraceptive methods should be considered for women with uncontrolled dyslipidemia.
- Patients using Balcoltra who have a significant change in headaches or who develop new headaches that are recurrent, persistent, or severe should be evaluated, and Balcoltra should be discontinued if indicated.
- Irregular bleeding and spotting sometimes occurs in patients on COCs, especially during the first three months of use. If bleeding persists or occurs after previously regular cycles on Balcoltra, check for causes such as pregnancy or malignancy.
- This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Sensitivity to tartrazine is frequently seen in patients who have aspirin hypersensitivity.

### Adverse Reactions

In a clinical trial with levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg, the most common adverse reactions (incidence ≥ 2%) were headache (14%), metrorrhagia (8%), dysmenorrhea (7%), nausea (7%), abdominal pain (4%), breast pain (4%), emotional lability (3%), acne (3%), depression (2%), amenorrhea (2%), and vaginal moniliasis (2%).

### Drug Interactions

Drugs or herbal products that induce certain enzymes, including cytochrome P450 3A4 (CYP3A4), may decrease the effectiveness of COCs or increase breakthrough bleeding.

**Patients should be counseled that COCs do not protect against HIV infection (AIDS) and other sexually transmitted diseases.**

**Please see accompanying full Prescribing Information, including BOXED WARNING (on reverse side), for Balcoltra.**

**References: 1.** Balcoltra [package insert]. Alpharetta, GA: Avion Pharmaceuticals LLC; 2018. **2.** Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations [database online]. Silver Spring, MD: US Food and Drug Administration; 2018. http://www.fda.gov/cder/ob/default.htm/. Updated February 2018. Accessed March 8, 2018. **3.** Archer DF, Maheux R, DelConte A, O'Brien FB; North American Levonorgestrel Study Group. Efficacy and safety of a low-dose monophasic combination oral contraceptive containing 100 µg levonorgestrel and 20 µg ethinyl estradiol (Alesse®). *Am J Obstet Gynecol.* 1999;181(5)(suppl):S39–S44. doi:10.1016/S0002-9378(99)70362-5.