RIGHT FROM THE START

Control and consistency

Balcoltra is a low-dose combination oral contraceptive that brings together long half-life, effective period control, and powerful pregnancy prevention for a total-package birth control she can count on.[1,2]

START WITH A LOW DOSE

Levonorgestrel: 0.1 mg[1]
Ethinyl estradiol: 0.02 mg[1]

A HALF-LIFE FOR HER LIFE

Elimination half-life of levonorgestrel: 34 ± 14 hours; ethinyl estradiol: 17 ± 5.7 hours[1]

PREDICTABLE PERIODS

4% incidence of breakthrough bleeding[1]

PREGNANCY PREVENTION

1/100 unintended pregnancies per woman-years[1]

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%).[1]

ORDER SAMPLES AND GET YOUR PATIENTS STARTED RIGHT AT BALCOLTRA.COM/HCP

Indications and Usage

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

Please see Important Safety Information on next page and Full Prescribing Information, including BOXED WARNING, on balcoltra.com/hcp.

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

SUPPORT EVERY STEP OF THE WAY WITH CO-PAY ASSISTANCE AND PATIENT SUPPORT

IMPORTANT SAFETY INFORMATION for Balcoltra® (levonorgestrel and ethinyl estradiol tablets and ferrous bisglycinate tablets)

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).

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.

For Full Prescribing Information, including BOXED WARNING and Patient Information, please visit balcoltra.com/hcp.

References: 1. Balcoltra [package insert]. Alpharetta, GA: Avion Pharmaceuticals, LLC; 2018. **2.** 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(suppl):S39-S44.

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Avion PHARMACEUTICALS

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