



Balcoltra™ (levonorgestrel/ethinyl estradiol/ferrous bisglycinate) – New drug approval

- On January 19, 2018, [Avion Pharmaceuticals announced the FDA approval of Balcoltra \(levonorgestrel/ethinyl estradiol/ferrous bisglycinate\)](#), for use by females of reproductive potential to prevent pregnancy.
- The efficacy of Balcoltra was demonstrated in a clinical study enrolling 1,477 women.
 - A total of 5 pregnancies were reported. This represents an overall pregnancy rate of approximately 1 pregnancy per 100 woman-years.
- Balcoltra carries a boxed warning for cigarette smoking and serious cardiovascular events.
- Balcoltra is contraindicated in patients with a high risk of arterial or venous thrombotic diseases, liver tumors or liver disease, undiagnosed abnormal uterine bleeding, pregnancy, breast cancer or other estrogen-or progestin-sensitive cancer, hypersensitivity of any of the components, co-administration with hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir.
- Additional warnings and precautions of Balcoltra include high blood pressure, gallbladder disease, carbohydrate and lipid metabolic effects, headache, bleeding irregularities and amenorrhea, allergic reactions to FD&C yellow No. 5, depression, carcinoma of the breast and cervix, effect on binding globulins, monitoring, hereditary angioedema, and chloasma.
- The most common adverse reactions ($\geq 2\%$) associated with Balcoltra use were headache (14%), metrorrhagia (8%), dysmenorrhea and nausea (7% each), abdominal pain and breast pain (4% each), emotional lability and acne (3% each), and depression, amenorrhea, and vaginal moniliasis (2% each).
- The recommended dosage of Balcoltra is one tablet orally at the same time every day in the order directed on the blister pack.
- Avion Pharmaceuticals plans to launch Balcoltra in the spring of 2018. Balcoltra will be available in a blister pack of 28 tablets. The 21 active tablets contain levonorgestrel 0.1 mg and ethinyl estradiol 0.02 mg and the 7 inactive tablets contain ferrous bisglycinate 36.5 mg.



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