

Important Risk Information, including BOXED WARNING

WARNING TO WOMEN WHO SMOKE

Do not use Balcoltra if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots, or stroke. This risk increases with age and the number of cigarettes you smoke.

Who should not take Balcoltra?

Do not use Balcoltra if you have or have had blood clots, history of heart attack or stroke, high blood pressure that medicine cannot control, breast cancer or any cancer which may be sensitive to female hormones, liver disease or liver tumors, unexplained bleeding from the vagina, hypersensitivity to any of the components, if you are or may be pregnant, or if you take Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, as this may increase levels of liver enzymes in the blood.

What else should I know about taking Balcoltra?

Treatment with Balcoltra should be stopped if you have a blood clot, and at least 4 weeks before and through 2 weeks after major surgery. You should not take Balcoltra any earlier than 4 weeks after having a baby. If you are breastfeeding, talk to your doctor before taking Balcoltra. If you experience yellowing of the skin or eyes due to problems with your liver, you should stop taking Balcoltra. If you are prediabetic or diabetic, your doctor should monitor you while using Balcoltra. Your doctor should evaluate you if you have any significant change in headaches or irregular menstrual bleeding. Balcoltra contains FD&C Yellow No. 5 and may cause an allergic reaction, including in those with an allergy to aspirin.

What are the most serious risks of taking Balcoltra?

Balcoltra increases the risk of serious conditions, including blood clots, stroke, and heart attack. These can be life-threatening and require immediate medical care.

What are the possible side effects of Balcoltra?

The most common side effects of Balcoltra are headache, spotting or bleeding between periods or no menstrual bleeding, nausea, breast tenderness or pain, stomach pain, pain during periods, depression, acne, and vaginal infections.

Birth control pills do not protect you against any sexually transmitted disease, including HIV, the virus that causes AIDS.

You may report side effects to Avion Pharmaceuticals, LLC at 1-888-612-8466 or to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including BOXED WARNING, at balcoltra.com/pi



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