



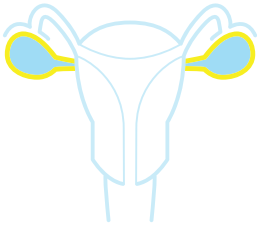
Balcoltra[®]
(levonorgestrel and ethinyl estradiol tablets, USP,
and ferrous bisglycinate tablets)
0.1mg/0.02mg and 36.5mg

What is Balcoltra[®]?

Balcoltra is a prescription birth control pill used for the prevention of pregnancy.

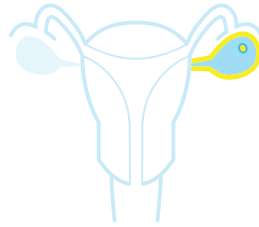
WARNING TO WOMEN WHO SMOKE
Do not use Balcoltra if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects (heart and blood vessel problems) from birth control pills, including death from heart attack, blood clots, or stroke. This risk increases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

Understanding Your Cycle



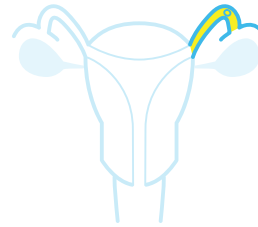
Egg cells

When women are born, their **ovaries** already contain all the egg cells they will have in their lifetime. They are held in pockets called follicles.¹



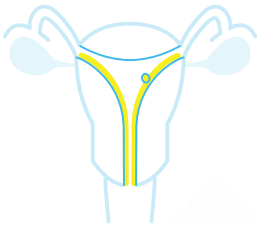
Hormones

At puberty, hormones—such as *follicle-stimulating hormone (FSH)* and *luteinizing hormone (LH)*—are released into the bloodstream. FSH and LH stimulate the production of **estrogen** and **progesterone** from the ovaries. Together, these hormones cause an egg to mature each month.¹⁻³



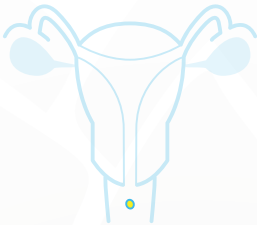
Ovulation

The release of the egg from the ovary is called **ovulation**. The egg travels down the **fallopian tube** to the **uterus** approximately once per month, with anywhere from 21- to 35-day cycles being considered normal.^{1,4}



Fertilization

If the egg meets a sperm while in the fallopian tube, *fertilization* may occur. The fertilized egg implants itself in the lining of the uterus (or **endometrium**), and the woman becomes pregnant.^{1,5}



Menstruation

If the egg cell is not fertilized, the endometrium detaches and is discharged along with some blood. This is known as *menstruation*—or your period. On average, it lasts 4 to 6 days.^{1,6}

IMPORTANT RISK INFORMATION

Who should not take Balcoltra?

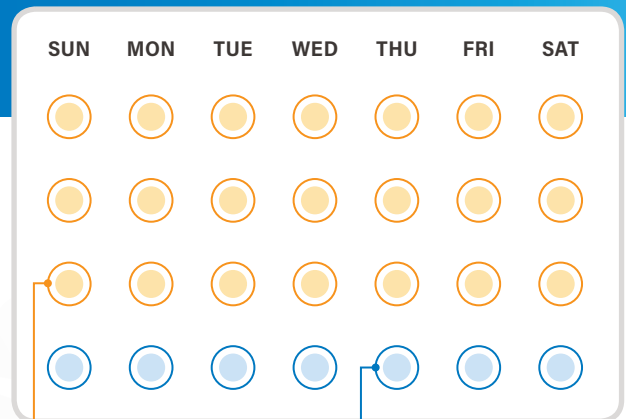
Do not use Balcoltra if you have or have had blood clots, history of heart attack or stroke, high blood pressure that medicine cannot control, breast cancer or any cancer that is sensitive to female hormones, liver disease or liver tumors, unexplained bleeding from the vagina, hypersensitivity to any 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.

Please see next page for continued Important Safety Information.

Please see Important Safety Information throughout and [click here for full Prescribing Information](#), including **BOXED WARNING**, and Patient Information.

How does Balcoltra affect the menstrual cycle?

The main way birth control pills prevent pregnancy is by stopping ovulation. Because women taking hormonal birth control are getting a continual dose of estrogen and progestin, FSH and LH are not released. Without these hormones, the egg does not mature and ovulation does not occur. The hormones in the birth control pills also thin the endometrium and thicken the cervical mucus.^{7,8}



Orange
0.1 mg levonorgestrel, 0.02 mg
ethinyl estradiol tablets

Blue
36.5 mg ferrous
bisglycinate tablets*

*The ferrous bisglycinate tablets do not serve any therapeutic purpose.

GLOSSARY

Breakthrough bleeding

Any bleeding that occurs during your monthly cycle, outside of your normal period. Light breakthrough bleeding is known as spotting.⁹

Cervix

The lower, narrower end of the uterus, which protrudes into the vagina.¹⁰

Endometrium

The mucous membrane lining the uterus.¹¹

Estrogens

Hormones that promote the regulation of the menstrual cycle and reproductive system, and maintain other female attributes.¹²

Fallopian tubes

Two tubes, located on either side of the uterus, that connect the ovaries to the uterus. After ovulation, an egg travels from the ovary to the uterus through one of the fallopian tubes.¹⁰

Ovaries

Two glands, located on either side of the uterus, that contain the eggs released at ovulation, and that produce hormones.¹⁰

Ovum

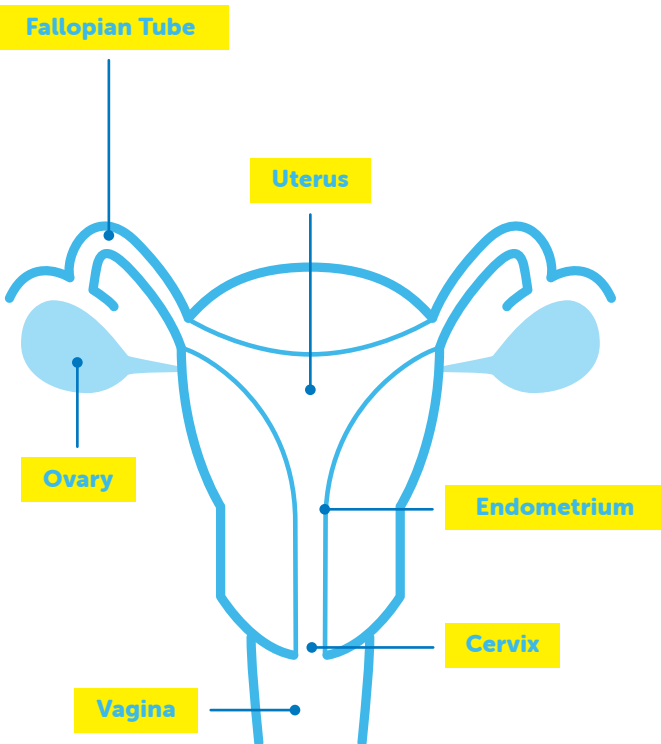
The female reproductive cell, sometimes called an "egg cell." The ovum is one of the largest cells in the human body, typically visible to the naked eye.¹³

Progestins

Progestins are a group of synthetic hormones that have effects similar to the natural hormone progesterone. Progestins work to inhibit ovulation, thicken cervical mucus, and thin the endometrium.⁸

Uterus

A muscular organ located in a woman's pelvis that contains and nourishes the developing fetus during pregnancy.¹⁴



IMPORTANT RISK INFORMATION (cont.)

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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the full [Prescribing Information](#), including **BOXED WARNING, and **Patient Information**.**

References: 1. Institute for Quality and Efficiency in Health Care. How does the menstrual cycle work? InformedHealth.org Web site. <https://www.informedhealth.org/how-does-the-menstrual-cycle-work.2114.en.html>. Published November 6, 2009. Updated August 10, 2016. Accessed June 6, 2018. 2. Society for Endocrinology. Follicle stimulating hormone. You and Your Hormones Web site. <http://www.yourhormones.info/hormones/follicle-stimulating-hormone/>. Updated February 2018. Accessed June 13, 2018. 3. Society for Endocrinology. Luteinising hormone. You and Your Hormones Web site. <http://www.yourhormones.info/hormones/luteinising-hormone/>. Updated February 2018. Accessed June 13, 2018. 4. Mayo Clinic Staff. Menstrual cycle: what's normal, what's not. Mayo Clinic Web site. <https://www.mayoclinic.org/healthy-lifestyle/womens-health/in-depth/menstrual-cycle/art-20047186>. Published May 11, 2016. Accessed June 13, 2018. 5. NICHD Office of Communications. About menstruation: What happens if a pregnancy occurs? Eunice Kennedy Shriver National Institute of Child Health and Human Development Web site. <https://www.nichd.nih.gov/health/topics/menstruation/conditioninfo>. Updated January 31, 2017. Accessed August 9, 2018. 6. Reed BG, Carr BR. The normal menstrual cycle and the control of ovulation. In: De Groot LJ, Chrousos G, Dungan K, et al, eds. *Endotext*. South Dartmouth, MA: MDText.com Inc; 2018. <http://www.endotext.org/chapter/the-normal-menstrual-cycle-and-the-control-of-ovulation/>. Updated May 22, 2015. Accessed July 16, 2018. 7. Van Cauwenberge JR. Hormonal contraception [in French] [abstract taken from *Rev Med Liege*. 1992;47(5):221-236]. PubMed Web site. <https://www.ncbi.nlm.nih.gov/pubmed/1604074>. Accessed June 15, 2018. 8. American College of Obstetricians and Gynecologists. Progestin-only hormonal birth control: pill and injection. American College of Obstetricians and Gynecologists Web site. <https://www.acog.org/Patients/FAQs/Progestin-Only-Hormonal-Birth-Control-Pill-and-Injection>. Updated March 2018. Accessed June 6, 2018. 9. 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. 10. American College of Obstetricians and Gynecologists. *Birth Control* [patient education pamphlet]. Washington, DC: American College of Obstetricians and Gynecologists; 2013. 11. Endometrium. Merriam-Webster Web site. <https://www.merriam-webster.com/dictionary/endometrium>. Updated May 25, 2018. Accessed June 8, 2018. 12. Nichols H. Everything you need to know about estrogen. MNT Knowledge Center, Medical News Today Web site. <https://www.medicalnewstoday.com/articles/277177.php>. Updated January 2, 2018. Accessed June 6, 2018. 13. Ovum. PubMed Health Web site. <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0030536/>. Accessed June 6, 2018. 14. Uterus. Merriam-Webster Web site. <https://www.merriam-webster.com/dictionary/uterus>. Updated July 15, 2018. Accessed July 18, 2018.