

UNDERSTANDING YOUR CYCLE

EGGS



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

HORMONES



At puberty, the body starts releasing follicle-stimulating hormone (FSH) and luteinizing hormone (LH). These stimulate the ovaries to produce **estrogen and progesterone**, which cause an egg to mature each month.¹⁻³

OVULATION



Once the egg is mature, it releases from the ovary to the **fallopian tube** and eventually the uterus in a process called ovulation. This happens about once per month, during the typical 21- to 35-day cycle.^{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 (or **endometrium**) of the uterus, and the woman becomes pregnant.^{1,5}

MENSTRUATION



If the egg 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



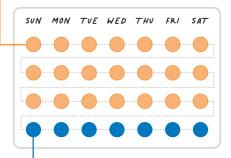


HOW DOES BALCOLTRA AFFECT THE MENSTRUAL CYCLE?

- Balcoltra prevents pregnancy through a continuous low dose of hormones that prevent FSH and LH from releasing, which stops ovulation⁷
- These hormones also thin the uterine lining and thicken the cervical mucus, which may lead to lighter periods and less breakthrough bleeding⁸

ORANGE PILLS

0.1 mg levonorgestrel, 0.02 mg ethinyl estradiol tablets



BLUE PILLS

36.5 mg ferrous bisglycinate tablets*

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

IMPORTANT RISK INFORMATION

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.

Please see Important Risk Information on reverse and Full Prescribing Information, including BOXED WARNING, and Patient Information on balcoltra.com.



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

KEY TERMS

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." 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

What is Balcoltra?

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

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

WARNING TO WOMEN WHO SMOKE

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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.

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 Full Prescribing Information, including BOXED WARNING, and Patient Information on balcoltra.com.

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. https://www.yourhormones.info/hormones/follicle-stimulating-hormone/. Updated February 2018. Accessed June 13, 2018. 4. Asop Clinic Staff. Menstrual cycle: what's normal, what's not. Mayo Clinic Web site. https://www.yourhormones.info/hormones/luteinising-hormone/. Updated February 2018. Accessed June 13, 2019. Accessed September 9, 2020. 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: Feingold KR, Anawalt B, Boyce A, et al., eds. Endotext. South Dartmouth, Mar. MoText.com Inc; 2018. https://www.endotext.org/chapter/the-normal-menstrual-cycle-and-the-control-of-ovulation. In. Feingold KR, Anawalt B, Boyce A, et al., eds. Endotext. South Dartmouth, Mar. MoText.com Inc; 2018. https://www.endotext.org/chapter/the-normal-menstrual-cycle-and-the-control-of-ovulation. In. Feingold KR, Anawalt B, Boyce A, et al., eds. Endotext. South Dartmouth, Mar. MoText.com Inc; 2018. https://www.endotext.org/chapter/the-normal-menstrual-cycle-and-the-control-of-ovulation. In. Feingold KR, Anawalt B, Boyce A, et al., eds. Endotext. South Dartmouth, Mar. MoText.com Inc; 2018. https://www.endotext.org/chapter/the-normal-menstrual-cycle-and-the-control-of-ovulation. Inc. Proceedings of the Control of ovulation. Inc. Proceedings of the Control of ovulation. Inc. Proceedings of the Control of ovulation. Inc. Proceedings of the Control of



