

PATIENT INFORMATION

Balcoltra[®] (BALL-coll-TRAA)

(levonorgestrel and ethinyl estradiol tablets, and ferrous bisglycinate tablets)
for oral administration

What is the most important information I should know about Balcoltra?

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.

What is Balcoltra?

Balcoltra is a birth control pill (oral contraceptive) used by women to prevent pregnancy.

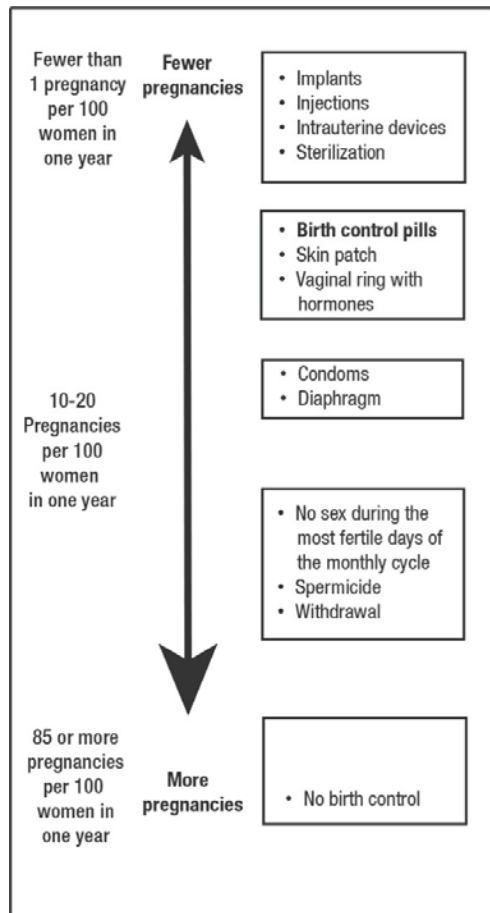
Balcoltra does **not** protect against HIV infections (AIDS) and other sexually transmitted infections.

How does Balcoltra work for contraception?

Your chance of getting pregnant depends on how well you follow the directions for taking your birth control pills. The better you follow the directions, the less chance you have of getting pregnant.

Based on the results of one clinical study of a 28-day regimen of levonorgestrel 0.1mg/ethinyl estradiol 0.02 mg tablets, about 1 out of 100 women may get pregnant within the first year they use Balcoltra.

The following chart shows the chance of getting pregnant for women who use different methods of birth control. Each box on the chart contains a list of birth control methods that are similar in effectiveness. The most effective methods are at the top of the chart. The box on the bottom of the chart shows the chance of getting pregnant for women who do not use birth control and are trying to get pregnant.



Do not take Balcoltra if you:

- smoke and are over 35 years of age
- have or have had blood clots in your arms, legs, lungs, or eyes
- have a problem with your blood that makes it clot more than normal
- have certain heart valve problems or irregular heart beat that increases your risk of having blood clots
- had a stroke
- had a heart attack
- have high blood pressure that cannot be controlled by medicine
- have diabetes with kidney, eye, nerve, or blood vessel damage
- have certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or any migraine headaches if you are over 35 years of age
- have liver problems, including liver tumors
- have any unexplained vaginal bleeding
- are pregnant
- have or have had breast cancer or any cancer that is sensitive to female hormones
- are allergic to levonorgestrel, ethinyl estradiol, ferrous bisglycinate or any of the ingredients in Balcoltra. Some people who are allergic to aspirin may also be allergic to FD&C Yellow No. 5 (tartrazine). FD&C Yellow No. 5 (tartrazine) is an ingredient in Balcoltra which also may cause an allergic type reaction such as bronchial asthma. See the end of this Patient Information leaflet for a complete list of ingredients in Balcoltra.
- take any Hepatitis C drug combination containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.

If any of these conditions happen while you are taking Balcoltra, stop taking Balcoltra right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking Balcoltra.

Before you take Balcoltra, tell your healthcare provider about all of your medical conditions, including if you:

- are scheduled for surgery. Balcoltra may increase your risk of blood clots after surgery. You should stop using your Balcoltra at least 4 weeks before you have surgery and not restart it until at least 2 weeks after your surgery.
- are pregnant or think you may be pregnant
- are depressed now or have been depressed in the past
- had yellowing of your skin or eyes (jaundice) caused by pregnancy (cholestasis of pregnancy)
- are breastfeeding or plan to breastfeed. Balcoltra may decrease the amount of breast milk you make. A small amount of the hormones in Balcoltra may pass into your breast milk. Talk to your healthcare provider about the best birth control method for you while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Balcoltra may affect the way other medicines work, and other medicines may affect how well Balcoltra works.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Balcoltra?

- Read the detailed Instructions for Use at the end of this Patient Information leaflet about the right way to take your Balcoltra.
- What are the possible serious side effects of Balcoltra?
- Like pregnancy, Balcoltra may cause serious side effects, including blood clots in your lungs, heart attack, or a stroke that may lead to death. Some other examples of serious blood clots include blood clots in the legs or eyes.

Serious blood clots can happen especially if you smoke, are obese, or are older than 35 years of age.

Serious blood clots are more likely to happen when you:

- first start taking birth control pills
- restart the same or different birth control pills after not using them for a month or more

Call your healthcare provider or go to a hospital emergency room right away if you have:

- leg pain that will not go away
- sudden severe shortness of breath
- sudden change in vision or blindness
- chest pain
- a sudden, severe headache unlike your usual headaches
- weakness or numbness in your arm or leg
- trouble speaking

Other serious side effects include:

- liver problems, including:
 - rare liver tumors
 - jaundice (cholestasis), especially if you previously had cholestasis of pregnancy. Call your healthcare provider if you have yellowing of your skin or eyes.

- **high blood pressure.** You should see your health care provider to check your blood pressure regularly.
- **gallbladder problems**
- **changes in the sugar and fat (cholesterol and triglycerides) levels in your blood**
- **new or worsening headaches including migraine headaches**
- **depression**
- **possible cancer in your breast and cervix**
- **swelling of your skin especially around your mouth, eyes, and in your throat (angioedema).**

Call your healthcare provider if you have a swollen face, lips, mouth tongue or throat, which may lead to difficulty swallowing or breathing. Your chance of having angioedema is higher if you have a history of angioedema.

- **dark patches of skin around your forehead, nose, cheeks and around your mouth, especially during pregnancy (chloasma).**

Women who tend to get chloasma should avoid spending a long time in sunlight, tanning booths, and under sun lamps while taking Balcoltra. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of Balcoltra?

The most common side effects of Balcoltra include:

- headache (including migraine)
- irregular vaginal bleeding (including absence of period)
- nausea
- breast tenderness, pain and discomfort
- stomach (abdominal) pain
- pain with your periods (menstrual cycle)
- mood changes, including depression
- acne
- vaginal infections

These are not all the possible side effects of Balcoltra. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at 1-800-FDA-1088.

What else should I know about taking Balcoltra?

- If you are scheduled for any lab tests, tell your healthcare provider you are taking Balcoltra. Certain blood tests may be affected by Balcoltra.

How should I store Balcoltra?

- Store Balcoltra at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Balcoltra and all medicines out of the reach of children.
- store away from light.

General information about the safe and effective use of Balcoltra.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet.

Do not use Balcoltra for a condition for which it was not prescribed. Do not give Balcoltra to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Balcoltra that is written for health professionals.

Do birth control pills cause cancer?

It is not known if hormonal birth control pills cause breast cancer. Some studies, but not all, suggest that there could be a slight increase in the risk of breast cancer among current users with longer duration of use.

If you have breast cancer now, or have had it in the past, do not use hormonal birth control because some breast cancers are sensitive to hormones.

Women who use birth control pills may have a slightly higher chance of getting cervical cancer. However, this may be due to other reasons such as having more sexual partners.

What if I want to become pregnant?

You may stop taking the pill whenever you wish. Consider a visit with your healthcare provider for a pre-pregnancy checkup before you stop taking the pill.

What should I know about my period when taking Balcoltra?

Some women may miss a period. Irregular vaginal bleeding or spotting may happen while you are taking Balcoltra, especially during the first few months of use. This usually is not a serious problem. If the irregular vaginal bleeding or spotting continues or happens again after you have had regular menstrual cycles call your healthcare provider. It is important to continue taking your pills on a regular schedule to prevent a pregnancy.

What if I miss my scheduled period when using Balcoltra?

Some women miss periods on hormonal birth control, even when they are not pregnant. However, if you go 2 or more months in a row without a period, or you

miss your period after a month where you did not use all of your Balcoltra correctly, call your healthcare provider because you may be pregnant. Also call your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. Stop taking Balcoltra if you are pregnant.

What are the ingredients in Balcoltra?

Active ingredients: Orange tablets: levonorgestrel and ethinyl estradiol.

Inactive ingredients: Orange tablets: FD&C Yellow #5 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, FD&C Red #40 Aluminum Lake, titanium dioxide, polyvinyl alcohol, talc, macrogol/ polyethylene glycol 3350 NF, lecithin (soya), iron oxide black, lactose monohydrate, magnesium stearate and pregelatinized starch.

Inactive ingredients: Blue tablets: ferrous bisglycinate, citric acid NF, glycine, water, maltodextrin NF, silica, microcrystalline cellulose NF, magnesium stearate NF, croscarmellose sodium NF, colloidal silicon dioxide NF, hypromellose type 2910, titanium dioxide, polyethylene glycol 400, FD&C Red #40 Aluminum Lake, FD&C Yellow #6 Aluminum Lake and FD&C Blue #1 Aluminum Lake.

For more information, go to www.avionrx.com or call 1-888-612-8466

INSTRUCTIONS FOR USE

Balcoltra® (BALL-coll-TRAA)

(levonorgestrel and ethinyl estradiol tablets, and ferrous bisglycinate tablets)
for oral administration

Important Information about taking Balcoltra

- Take **1** pill every day at the same time. Take the pills in the order directed on your blister pack.

Both the orange pills and the blue pills should be swallowed whole.

- Do not skip your pills, even if you do not have sex often. If you miss pills (including starting the pack late) **you could get pregnant**. The more pills you miss, the more likely you are to get pregnant.
- If you have trouble remembering to take Balcoltra, talk to your healthcare provider. When you first start taking Balcoltra, spotting or light bleeding in between your periods may occur. Contact your healthcare provider if this does not go away after a few months.
- You may feel sick to your stomach (nauseous), especially during the first few months of taking Balcoltra. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If your nausea does not go away, call your healthcare provider.
- Missing pills can also cause spotting or light bleeding, even when you take the missed pills later. On the days you take **2** pills to make up for missed pills (see below), you could also feel a little sick to your stomach.
- Some women miss periods on hormonal birth control, even when they are not pregnant. However, if you miss a period and have not taken Balcoltra according to directions, or miss 2 periods in a row, or feel like you may be pregnant, call your health care provider. If you have a positive pregnancy test, you should stop taking Balcoltra.
- If you have vomiting or diarrhea within **3 to 4** hours of taking your pill, take another pill of the same color from your extra blister pack. If you do not have an extra blister pack, take the next pill in your blister pack.
- Continue taking all your remaining pills in order. Start the first pill of your next blister pack the day after finishing your current blister pack. This will be 1 day earlier than originally scheduled. Continue on your new schedule.
- If you have vomiting or diarrhea for more than 1 day, your birth control pills may not work as well. Use an additional birth control method, like condoms or a spermicide, until you check with your healthcare provider.
- Stop taking Balcoltra at least 4 weeks before you have major surgery and do not restart it until at least 2 weeks after your surgery. Be sure to use other forms of contraception (like condoms or spermicide) during this time period.

Before you start taking Balcoltra

- Decide what time of day you want to take your pill. It is important to take it at the same time every day and in the order as directed on your blister pack.
- Have backup contraception (condoms or spermicide) available and an extra full pack of pills as needed.

When should I start taking Balcoltra?

If you start taking Balcoltra and you have not used a hormonal birth control method before:

- There are 2 ways to start taking your birth control pills.
 - You can either start on a Sunday (Sunday Start) or
 - You can start on the first day (Day 1) of your natural menstrual period (Day 1 Start).

Your healthcare provider should tell you when to start taking your birth control pill.

If you use the Sunday Start, use non-hormonal back-up contraception such as condoms or spermicide for the first 7 days that you take Balcoltra. You do not need back-up contraception if you use the Day 1 Start.

If you start taking Balcoltra and you are switching from another birth control pill:

- Start your new Balcoltra pack on the same day that you would start the next pack of your previous birth control method.
- Do not continue taking the pills from your previous birth control pack.

If you start taking Balcoltra and previously used a vaginal ring or transdermal patch:

- Start using Balcoltra on the day you would have reapplied the next ring or patch.

If you start taking Balcoltra and you are switching from a progestin-only method such as an implant or injection:

- Start taking Balcoltra on the day of removal of your implant or on the day when you would have had your next injection.

If you start taking Balcoltra and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking Balcoltra on the day of removal of your IUD or IUS.
- You do not need back-up contraception if your IUD or IUS is removed on the first day (Day 1) of your period. If your IUD or IUS is removed on any other day, use non-hormonal back-up contraception such as condoms or spermicide for the first 7 days that you take Balcoltra.

Keep a calendar to track your period:

If this is the first time you are taking birth control pills, read, “When should I start taking Balcoltra?” above. Follow these instructions for either a **Sunday Start** or a **Day 1 Start**.

Sunday Start:

You will use a **Sunday Start** if your healthcare provider told you to take your first pill on a Sunday.

Use non-hormonal back-up contraception such as condoms or spermicide for the first 7 days of the first cycle that you take Balcoltra.

Instructions for using your pill pack

- Look at your Balcoltra pill pack. See **Figure A**.
- Take pill 1 on the Sunday **after your period starts**.
- If your period starts on a Sunday, take pill “1” that day and refer to Day 1 Start instructions below.
- Take 1 pill every day in the order on the blister pack at the same time each day for **28** days.
- After taking the last pill on **Day 28** from the blister pack, start taking the first pill from a new pack, on the same day of the week as the first pack (Sunday). Take the first pill in the new pack whether or not you are having your period.

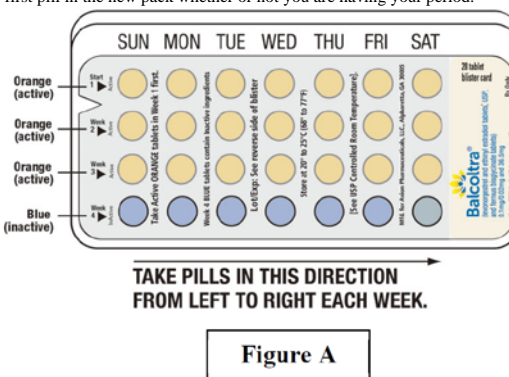


Figure A

Day 1 Start:

You will use a **Day 1 Start** if your healthcare provider told you to take your first pill (Day 1) on the **first day of your period**.

- Take **1** pill every day in the order as shown on the pill dispenser, at the same time each day, for **28** days.
- After taking the last pill on **Day 28** from the pill dispenser, start taking the first pill from a new pack, on the same day of the week as the first pack. Take the first pill in the new pack whether or not you are having your period.

Instructions for using your pill pack:

Step 1.

Look at your Balcoltra pill pack. See **Figure A**. The Balcoltra pill pack has:

- 21** orange (active) pills with hormone for **Week 1 through Week 3**.
- 7** blue (inactive) pills without hormones for **Week 4**

Step 2.

Find what day of the week you are to start taking pills. If your period begins on a day other than Sunday, place the day label strip that starts with the first day of your period. For example, if your period begins on Monday, place the day label strip with Monday as the first day. See **Figure B**.

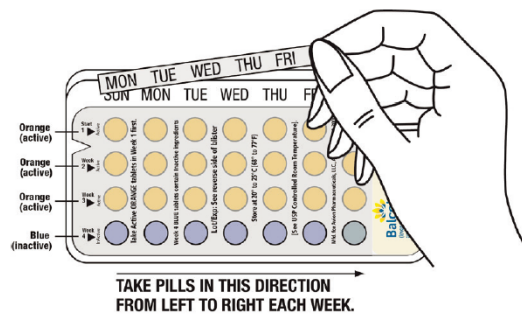


Figure B

Step 3.

Remove the orange pill by pressing the pill through the foil in the bottom of the pill pack. Continue taking the orange pills for 21 days.

Step 4.

On the first day of **Week 4** start taking the blue pills. Take the blue pill for 7 days. Your period should start during this time.

Step 5.

When you have taken all of the blue pills in your pill pack, get a new pill pack and start taking the orange pills.

• **For a Day 1 start:**

Begin your next pill pack on the same day of the week as your first cycle pill pack.

• **For a Sunday Start:**

Begin your next pill pack on Sunday.

What should I do if I miss any Balcitra pills?

If you miss 1 pill in Weeks 1, 2, or 3, follow these steps:

- Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.
- Then continue taking 1 pill every day until you finish the pack.
- You do not need to use a back-up birth control method if you have sex.

If you miss 2 pills in Week 1 or Week 2 of your pack, follow these steps:

- Take the 2 missed pills as soon as possible and the next 2 pills the next day.
- Then continue to take 1 pill every day until you finish the pack.
- Use a non-hormonal birth control method (such as a condom or spermicide) as a back-up if you have sex during the first 7 days after missing your pills.

If you miss 2 pills in a row in Week 3, or you miss 3 or more pills in a row during Weeks 1, 2, or 3 of the pack, follow these steps:

- **If you are a Day 1 Starter:**
 - Throw out the rest of the pill pack and start a new pack that same day.
- **If you are a Sunday Starter:**
 - Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.
- You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your healthcare provider because you might be pregnant.
- You could become pregnant if you have sex during the first 7 days after you restart your pills. You should use a non-hormonal birth control method (such as a condom or spermicide) as a back-up if you have sex during the first 7 days after you restart your pills.

If you have any questions or are unsure about the information in this leaflet, call your healthcare provider. They have a more technical leaflet called the Professional Labeling which you may wish to read.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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