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Patient Information

Levonorgestrel and Ethinyl Estradiol [LEE-voe-nor-JES-trel and EH-thih-nill-ess-tra-DYE-ole] Tablets, 0.15 mg/0.03 mg

WARNING TO WOMEN WHO SMOKE

Do not use levonorgestrel and ethinyl estradiol tablets if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects 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 the most important information I should know about levonorgestrel and ethinyl estradiol tablets?

Do not use levonorgestrel and ethinyl estradiol tablets if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects from hormonal 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 are levonorgestrel and ethinyl estradiol tablets?

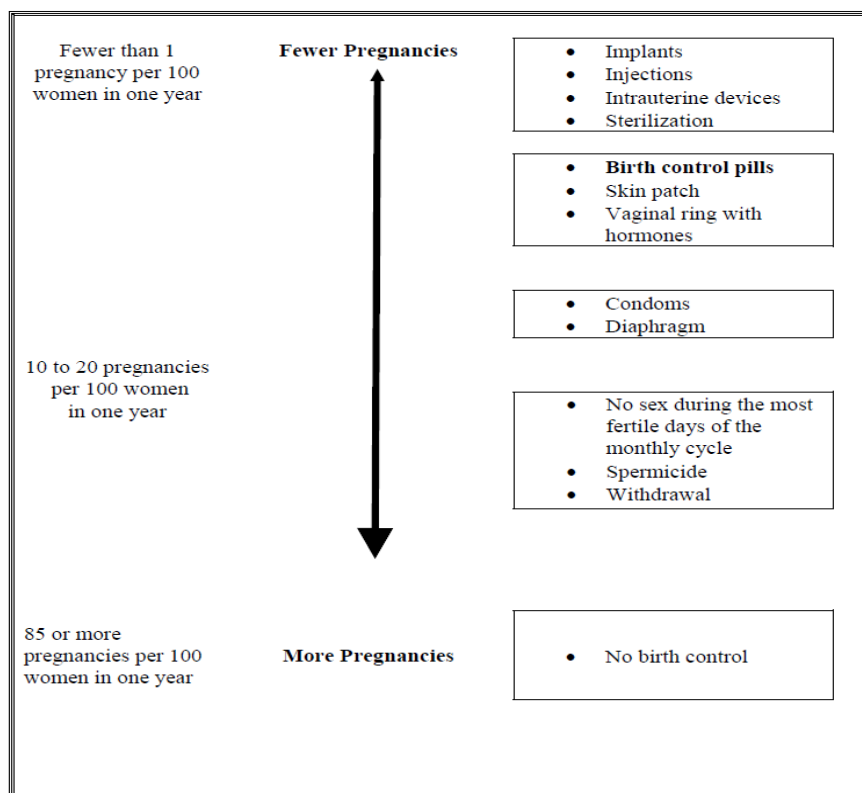
Levonorgestrel and ethinyl estradiol tablet is a birth control pill (oral contraceptive) used by women to prevent pregnancy. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called levonorgestrel. Levonorgestrel and ethinyl estradiol tablet does not protect against HIV infections (AIDS) and other sexually transmitted infections.

How does levonorgestrel and ethinyl estradiol tablet 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 clinical studies, about 1 to 5 out of 100 women may get pregnant during the first year they use levonorgestrel and ethinyl estradiol tablets.

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.



Who should not take levonorgestrel and ethinyl estradiol tablets?

Do not take levonorgestrel and ethinyl estradiol tablets if you:

- smoke and are over 35 years of age
- have or had blood clots in your arms, legs, lungs, or eyes
- had a stroke
- had a heart attack
- have certain heart valve problems or heart rhythm abnormalities that can cause blood clots to form in the heart
- have or had a problem with your blood that makes it clot more than normal
- have high blood pressure that cannot be controlled by medicine or have high blood pressure with blood vessels problems
- have diabetes
 - and are over the age of 35
 - with high blood pressure
 - with kidney, eye, nerve, or blood vessel damage
 - for more than 20 years
- 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 or had breast cancer
- have liver problems, including liver tumors
- have any unexplained vaginal bleeding

- 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 to you while you are taking levonorgestrel and ethinyl estradiol tablets, stop taking levonorgestrel and ethinyl estradiol tablets right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking levonorgestrel and ethinyl estradiol tablets.

What should I tell my healthcare provider before taking levonorgestrel and ethinyl estradiol tablets?

Tell your healthcare provider if you:

- are pregnant or think you may be pregnant
- are scheduled for surgery. Levonorgestrel and ethinyl estradiol tablets may increase your risk of blood clots after surgery. You should stop taking levonorgestrel and ethinyl estradiol tablets at least 4 weeks before you have surgery and not restart levonorgestrel and ethinyl estradiol tablets until at least 2 weeks after your surgery.
- 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. Levonorgestrel and ethinyl estradiol tablets may decrease the amount of breast milk you make. A small amount of the hormones in levonorgestrel and ethinyl estradiol tablets 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 if you have ever had any of the conditions listed in, “**Who should not take Levonorgestrel and ethinyl estradiol tablets**” above. Your healthcare provider may recommend another method of birth control.

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

Levonorgestrel and ethinyl estradiol tablets may affect the way other medicines work, and other medicines may affect how well levonorgestrel and ethinyl estradiol tablets works.

Some medicines and herbal products may make birth control pills less effective, including:

- barbiturates
- bosentan
- carbamazepine
- felbamate
- griseofulvin
- oxcarbazepine
- phenytoin
- rifampin
- St. John’s wort
- topiramate

Use a back-up or alternative birth control method when you take medicines that may make birth control pills less effective.

Birth control pills may interact with lamotrigine, an anticonvulsant used for epilepsy. This may increase the risk of seizures, so your physician may need to adjust the dose of lamotrigine.

Women on thyroid hormone replacement therapy may need increased doses of thyroid hormone.

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 levonorgestrel and ethinyl estradiol tablets?

Read the Instructions for Use at the end of this Patient Information.

What are the most serious risks of taking levonorgestrel and ethinyl estradiol tablets?

- **Like pregnancy, levonorgestrel and ethinyl estradiol tablets 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
- yellowing of your skin or eyes

Other serious side effects include:

- **liver problems, including:**
 - rare liver tumors
 - jaundice (cholestasis), especially if you previously had cholestasis of pregnancy.
- **high blood pressure.** You should see your healthcare provider to check of 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**
- **irregular or unusual vaginal bleeding and spotting between your menstrual periods, especially during the first 3 months of taking levonorgestrel and ethinyl estradiol tablets.**
- **depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself.**

- **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 levonorgestrel and ethinyl estradiol tablets. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of levonorgestrel and ethinyl estradiol tablets?

- headache (migraine)
- heavier or longer periods, pain with periods
- nausea
- acne
- breast tenderness
- increase in weight

These are not all the possible side effects of levonorgestrel and ethinyl estradiol tablets. For more information, ask your healthcare provider or pharmacist.

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

What else should I know about taking levonorgestrel and ethinyl estradiol tablets?

- If you are scheduled for any lab tests, tell your healthcare provider you are taking levonorgestrel and ethinyl estradiol tablets. Certain blood tests may be affected by levonorgestrel and ethinyl estradiol tablets.
- Do not skip any pills, even if you do not have sex often.
- Birth control pills should not be taken during pregnancy. However, birth control pills taken by accident during pregnancy are not known to cause birth defects.
- You should stop levonorgestrel and ethinyl estradiol tablets at least four weeks before you have major surgery and not restart it for at least two weeks after the surgery, due to an increased risk of blood clots.
- If you are breastfeeding, consider another birth control method until you are ready to stop breastfeeding. Birth control pills that contain estrogen, like levonorgestrel and ethinyl estradiol tablets, may decrease the amount of milk you make. A small amount of the pill's hormones pass into breast milk, but this has not caused harmful effects in breastfeeding infants.
- If you have vomiting or diarrhea, your birth control pills may not work as well. Use another birth control method, like condoms or a spermicide, until you check with your healthcare provider.

How should I store levonorgestrel and ethinyl estradiol tablets?

- Store levonorgestrel and ethinyl estradiol tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.
- Keep levonorgestrel and ethinyl estradiol tablets and all medicines out of the reach of children.

General information about the safe and effective use of levonorgestrel and ethinyl estradiol tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use levonorgestrel and ethinyl estradiol tablets for a condition for which it was not prescribed. Do not give levonorgestrel and ethinyl estradiol tablets to other people, even if they have the same symptoms that you have.

This Patient Information summarizes the most important information about levonorgestrel and ethinyl estradiol tablets. You can ask your pharmacist or healthcare provider for information about levonorgestrel and ethinyl estradiol tablets that is written for health professionals.

For more information, call Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at www.lupinpharmaceuticals.com.

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 levonorgestrel and ethinyl estradiol tablets?

When you take levonorgestrel and ethinyl estradiol tablets, which have a 91-day extended dosing cycle, you should have 4 scheduled periods a year (bleeding when you are taking the 7 white pills). However, you will probably have more bleeding or spotting between your scheduled periods than if you were using a birth control pill with a 28-day dosing cycle. During the first levonorgestrel and ethinyl estradiol tablets 91-day treatment cycle, about 1 in 3 women may have 20 or more days of unplanned bleeding or spotting. This bleeding or spotting tends to decrease with time. **Do not** stop taking levonorgestrel and ethinyl estradiol tablets because of this bleeding or spotting. If the spotting continues for more than 7 days in a row or if the bleeding is heavy, call your healthcare provider.

What if I miss my scheduled period when taking levonorgestrel and ethinyl estradiol tablets?

You should consider the possibility that you are pregnant if you miss your scheduled period (no bleeding on the days that you are taking white pills). Since scheduled periods are less frequent when you are taking levonorgestrel and ethinyl estradiol tablets, notify your healthcare provider that you have missed your period and that you are taking levonorgestrel and ethinyl estradiol tablets. Also notify your healthcare provider if you have symptoms of pregnancy such as morning sickness or unusual breast tenderness. It is important that your healthcare provider evaluates you to determine if you are pregnant. Stop taking levonorgestrel and ethinyl estradiol tablets if it is determined that you are pregnant.

What are the ingredients in levonorgestrel and ethinyl estradiol tablets?

Active ingredients: Each pink pill contains levonorgestrel and ethinyl estradiol.

Inactive ingredients:

Pink pills: croscarmellose sodium, FD & C Blue # 1, FD & C Red # 40, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and titanium dioxide.

White pills: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Instructions For Use
Levonorgestrel and Ethinyl Estradiol [LEE-voe-nor-JES-trel and EH-thih-nill-ess-tra-DYE-ole] Tablets

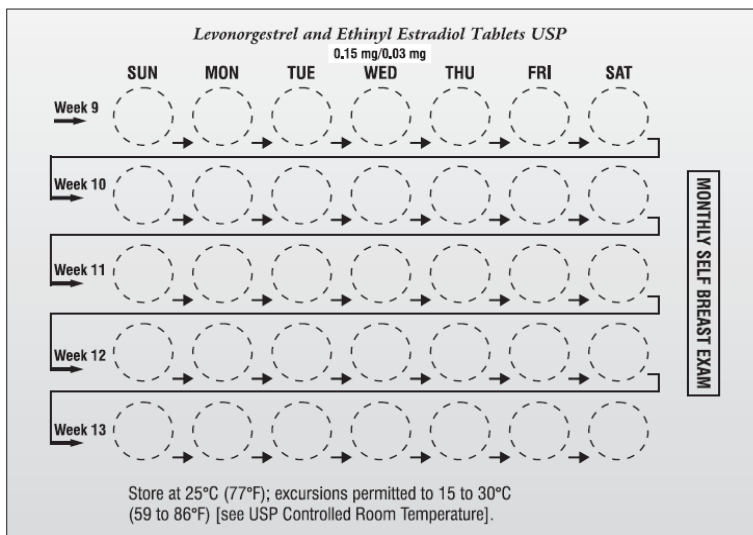
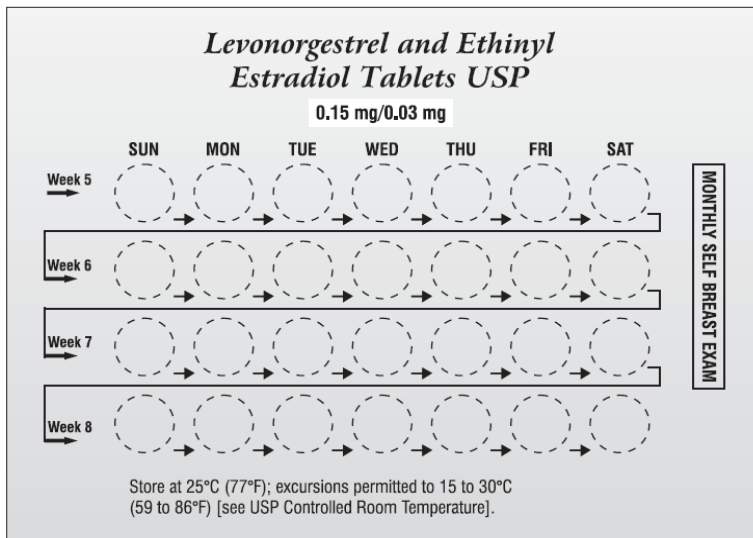
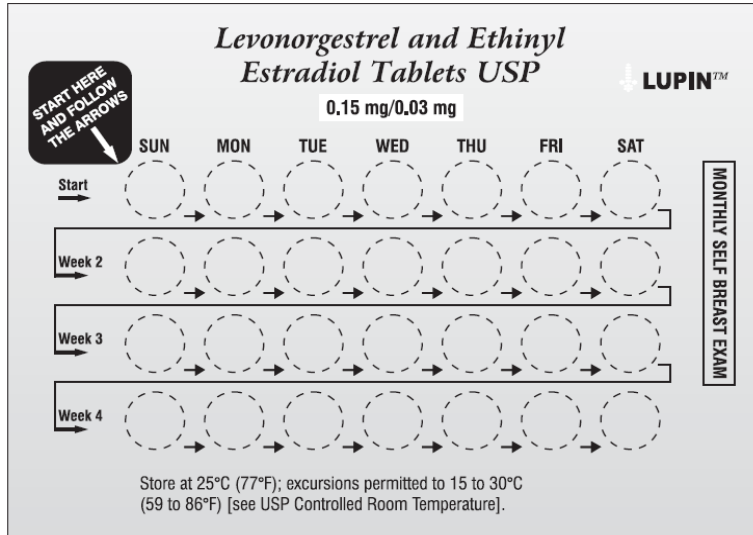
Important information about taking levonorgestrel and ethinyl estradiol tablets

- Take **1** pill every day at the same time. Take the pills in the order directed on your wallet.
- 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 levonorgestrel and ethinyl estradiol tablets, talk to your healthcare provider.
- When you first start taking levonorgestrel and ethinyl estradiol tablets, 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 levonorgestrel and ethinyl estradiol tablets. 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, “**What should I do if I miss any levonorgestrel and ethinyl estradiol pills?**” below), you could also feel a little sick to your stomach.
- It is not uncommon to miss a period. However, if you miss a period and have not taken levonorgestrel and ethinyl estradiol tablets according to directions, or feel like you may be pregnant, call your healthcare provider. If you have a positive pregnancy test, you should stop taking levonorgestrel and ethinyl estradiol tablets.
- If you have vomiting or diarrhea within **3 to 4** hours of taking a pink pill, take another pink pill as soon as possible. Continue taking one pill a day until the 91-day course is finished.
- 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 spermicide, until you check with your healthcare provider.
- Stop taking levonorgestrel and ethinyl estradiol tablets at least **4** weeks before you have major surgery and do not restart after the surgery without asking your healthcare provider. Be sure to use other forms of contraception (like condoms or spermicide) during this time period.

Before you start taking levonorgestrel and ethinyl estradiol tablets:

- Decide what time of day you want to take your pill. It is important to take it at about the same time every day.
- Look at your Extended-Cycle Wallet. Your Wallet consist of blister strips that hold 91 individually sealed pills (a 13-week, or 91-day, cycle). The 91 pills consist of 84 pink pills (active pills with hormones) and 7 white pills (inactive pills without hormone).
- Blister strip 1 and 2 each contain 28 pink pills (4 rows of 7 pills). **See Figure A.**
- Blister strip 3 contains 35 pills consisting of 28 pink pills (4 rows of 7 pills) and 7 white pills (1 row of 7 pills). **See Figure A.**

Figure A



- Also find:
 - Where on the first blister strip in the pack to start taking pills (upper left corner at the start arrow) and
 - In what order to take the pills (follow the weeks and arrow)
- Be sure you have ready at all times another kind of birth control (such as condoms or spermicide), to use as a back-up in case you miss pills.

When should I start taking levonorgestrel and ethinyl estradiol tablets?

If you start taking levonorgestrel and ethinyl estradiol tablets and you have not used a hormonal birth control method before:

- Take the first pink pill on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the first pink pill that same day.
- Use another method of birth control (such as condoms or spermicides) as a back-up method if you have sex anytime from the Sunday you start your first pink pill until the next Sunday (first 7 days).

If you have recently given birth and have not yet had a period, use another method of birth control if you have sex (such as condoms and spermicides) as a back-up method until you have taken levonorgestrel and ethinyl estradiol tablets for 7 days.

If you start taking levonorgestrel and ethinyl estradiol tablets and you are switching from another birth control pill:

- Start your new levonorgestrel and ethinyl estradiol tablets 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 levonorgestrel and ethinyl estradiol tablets and previously used a vaginal ring:

- Start using levonorgestrel and ethinyl estradiol tablets on the day you would have reapplied the next ring.

If you start taking levonorgestrel and ethinyl estradiol tablets and previously used a transdermal patch:

- Start using levonorgestrel and ethinyl estradiol tablets on the day you would have started a new cycle (first patch application).

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

- Start taking levonorgestrel and ethinyl estradiol tablets on the day of removal of your implant, or on the day when you would have had your next injection.

If you start taking levonorgestrel and ethinyl estradiol tablets and you are switching from an intrauterine device or system (IUD or IUS):

- Start taking levonorgestrel and ethinyl estradiol tablets 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 levonorgestrel and ethinyl estradiol tablets.

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 levonorgestrel and ethinyl estradiol tablets?**” above. Follow these instructions for a **Sunday Start**.

Instructions for using your levonorgestrel and ethinyl estradiol tablets Extended-Cycle Wallet:

Sunday Start:

- Take pill **1** on the Sunday **after your period starts**. To remove your pill from the wallet, press the pill through the hole in the bottom of the wallet.
- If your period starts on a Sunday, take pill “**1**” that same day.
- Take **1** pill at about the same time every day until you have taken the last pill in the wallet.
- After taking the last white pill on Day 91 from the wallet, start taking the first pink pill from a new Extended-Cycle Wallet on the very next day (this should be a Sunday). Take the first pill in the new pack whether or not you are having your period.
- Use non-hormonal back-up contraception such as condoms or spermicide for the first 7 days of the first cycle that you take levonorgestrel and ethinyl estradiol tablets.

What should I do if I miss any levonorgestrel and ethinyl estradiol pills?

If you miss 1 pink pill, 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 pink pills in a row, follow these steps:

- Take **2** pills on the day you remember and **2** pills the next day.
- Then continue to take **1** pill every day until you finish the pack.
- You could become pregnant if you have sex in the **7** days after you miss two pills. You **must** 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 miss 3 or more pink pills in a row, follow these steps:

- **Do not** take the missed pills. Keep taking **1** pill every day until you have completed all of the remaining pills in the pack. For example, if you start taking the pill on Thursday, take the pill under “Thursday” and do not take the missed pills. You may have bleeding during the week following the missed pills.
- You could become pregnant if you have sex during the days of missed pills or during the first 7 days after restarting your pills. You **must** use a non-hormonal birth control method (such as a condom or spermicide) as a back-up when you miss pills and for the first **7** days after you

restart your pills. If you do not have your period when you are taking the white pills, call your healthcare provider because you may be pregnant.

If you miss any of the 7 white pills:

- Throw away the missed pills.
- Keep taking the scheduled pills until the pack is finished.
- You do not need a back-up method of birth control.

Finally, if you are still not sure what to do about the pills you have missed

- Use a back-up method anytime you have sex.
- Keep taking one pill each day until you contact your healthcare provider.

If you have any questions or are unsure about the information in this leaflet, call your healthcare provider.

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



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