

## FDA Approved Patient Labeling

### PATIENT INFORMATION

#### Levonorgestrel and Ethinyl Estradiol Tablet and Ethinyl Estradiol Tablet

##### WARNING TO WOMEN WHO SMOKE

**Do not use levonorgestrel and ethinyl estradiol tablets 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 and Ethinyl Estradiol Tablets?**

**Do not use levonorgestrel and ethinyl estradiol tablets 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 Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets?**

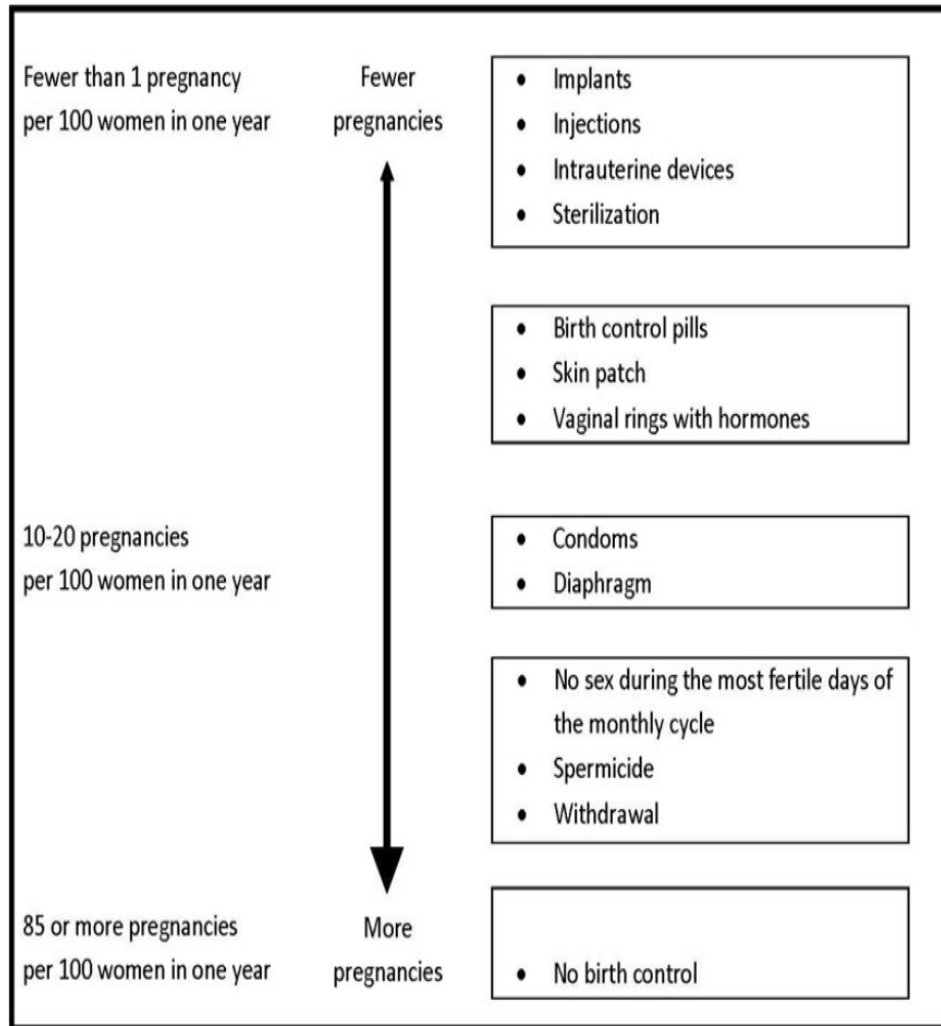
levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets is a birth control pill (hormonal contraceptive) used by women to prevent pregnancy. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called levonorgestrel. levonorgestrel and ethinyl estradiol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

**How does levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets work for contraception?**

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

Based on the results of a single clinical study lasting 12 months, 2 to 4 women, out of 100 women, may get pregnant during the first year they use Levonorgestrel and Ethinyl Estradiol Tablets 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 and ethinyl estradiol tablets?**

Do not take levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets if you:

- smoke and are over 35 years of age
- have or had blood clots in your arms, legs, eyes or lungs
- 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 an inherited 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 vessel problems
- have diabetes and are over the age of 35; have diabetes with high blood pressure; kidney, eye, nerve, or blood vessel damage; or 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 the age of 35
- have or had breast cancer

- have liver disease, including liver tumors
- have 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 and ethinyl estradiol tablets, stop taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets right away and talk to your healthcare provider. Use non-hormonal contraception (such as condoms and spermicide) when you stop taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets.**

**What should I tell my healthcare provider before taking levonorgestrel and ethinyl estradiol tablets 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 and ethinyl estradiol tablets may increase your risk of blood clots after surgery. You should stop taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets at least 4 weeks before you have surgery and not restart levonorgestrel and ethinyl estradiol tablets 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 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 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 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 and ethinyl estradiol tablets may affect the way other medicines work, and other medicines may affect how well levonorgestrel and ethinyl estradiol tablets 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 and ethinyl estradiol tablets?**

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

### **What are the most serious risks of taking birth control pills?**

Like pregnancy, birth control pills increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age over 35 years old. It is possible to die from a problem caused by a blood clot, such as a heart attack or a stroke. Some examples of serious blood clots are blood clots in the:

- Legs (thrombophlebitis)
- Lungs (pulmonary embolus)
- Eyes (loss of eyesight)
- Heart (heart attack)
- Brain (stroke)

A few women who take birth control pills may get:

- High blood pressure. You should see your healthcare provider to check your blood pressure regularly.
- Gallbladder problems
- Rare cancerous or noncancerous liver tumors

All of these events are uncommon in healthy women.

**Call your healthcare provider right away if you have:**

- Persistent leg pain
- Sudden shortness of breath
- Sudden blindness, partial or complete
- Severe pain in your chest
- Sudden, severe headache unlike your usual headaches
- Weakness or numbness in an arm or leg, or trouble speaking
- Yellowing of the skin or eyes

### **What are common side effects of birth control pills?**

The most common side effects of birth control pills are:

- Spotting or bleeding between menstrual periods
- Nausea
- Breast tenderness
- Headache

These side effects are usually mild and usually disappear with time.

Less common side effects are:

- Acne
- Less sexual desire
- Bloating or fluid retention
- Blotchy darkening of the skin, especially on the face
- High blood sugar, especially in women who already have diabetes
- High fat levels in the blood.
- Depression, especially if you have had depression in the past. Call your healthcare provider immediately if you have any thoughts of harming yourself.
- Problems tolerating contact lenses
- Weight changes

This is not a complete list of possible side effects. Talk to your healthcare provider if you develop any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

No serious problems have been reported from a birth control pill overdose, even when accidentally taken by children.

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

- If you are scheduled for any lab tests, tell your healthcare provider you are taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets. Certain blood tests may be affected by levonorgestrel and ethinyl estradiol tablets 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 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 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 and ethinyl estradiol tablets?**

- Store levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep levonorgestrel and ethinyl estradiol tablets 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 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 and ethinyl estradiol tablets for a condition for which it was not prescribed. Do not give levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets to anyone else.

This Patient Information summarizes the most important information about levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets. If you have concerns or questions, ask your healthcare provider. You may also ask your healthcare providers for a more detailed label written for medical 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 levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets?**

When you take levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets, which has a 91-day extended dosing cycle, you should expect to have 4 scheduled periods per year (bleeding when you are taking the 7 mustard pills). Each period is likely to last about 2 to 3 days. 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. This bleeding or spotting tends to decrease with time. Do not stop taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets because of this bleeding or spotting. If the spotting continues for more than 7 consecutive days or if the bleeding is heavy, call your healthcare provider.

### **What if I miss my scheduled period when taking levonorgestrel and ethinyl estradiol tablets 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 mustard tablets). Since scheduled periods are less frequent when you are taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets, notify your healthcare provider that you have missed your period and that you are taking levonorgestrel and ethinyl estradiol tablets 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 and ethinyl estradiol tablets if it is determined that you are pregnant.

### **What are the ingredients in levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets?**

#### **Active ingredients:**

Orange tablets: levonorgestrel and ethinyl estradiol

mustard tablets: ethinyl estradiol

#### **Inactive ingredients:**

Orange tablets: FD&C Yellow # 6 (Sunset Yellow) aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, corn starch, titanium dioxide and triacetin.  
mustard tablets: anhydrous lactose, FD&C Yellow # 10 aluminum lake, FD&C Yellow # 6 (Sunset Yellow) aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol, polysorbate 80 and titanium dioxide.

## INSTRUCTIONS FOR USE

### LEVONORGESTREL AND ETHINYL ESTRADIOL TABLETS AND ETHINYL ESTRADIOL TABLETS

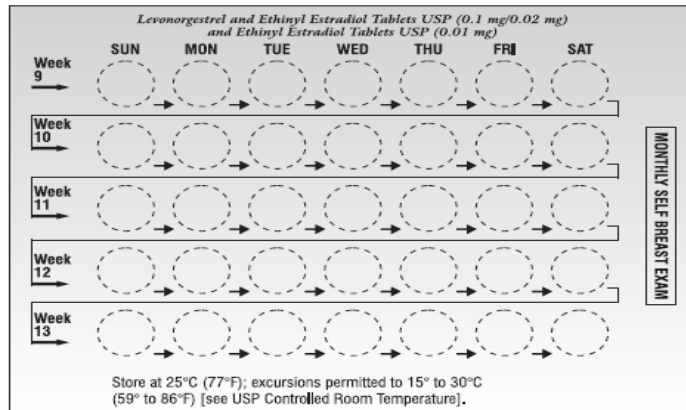
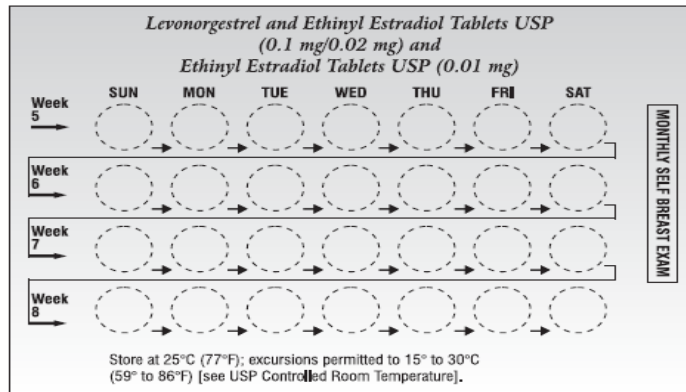
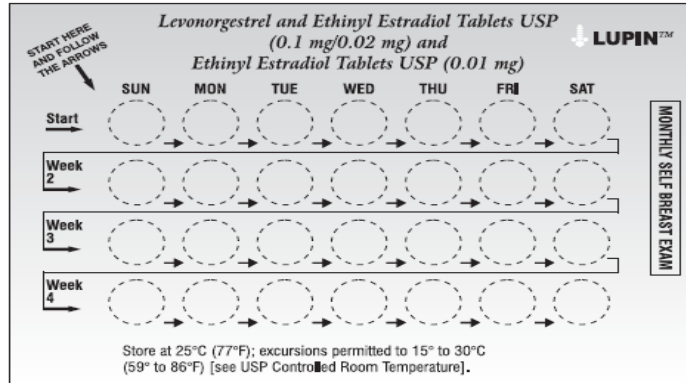
#### **How do I take Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets?**

1. Take one pill every day at the same time. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.
2. Many women have spotting or light bleeding, or may feel sick to their stomach during the first few months of taking levonorgestrel and ethinyl estradiol tablet and ethinyl estradiol tablet. If you feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn't go away, check with your healthcare provider.
3. 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, you could also feel a little sick to your stomach.
4. If you have trouble remembering to take levonorgestrel and ethinyl estradiol tablet and ethinyl estradiol tablet, talk to your healthcare provider about how to make pill-taking easier or about using another method of birth control.

#### **Before you start taking Levonorgestrel and Ethinyl Estradiol tablets and Ethinyl Estradiol tablets**

1. Decide what time of day you want to take your pill. It is important to take it at about the same time every day.
2. Look at your Extended-Cycle Wallet. Your wallet consists of blister strips that hold 91 individually sealed pills (a 13-week or 91-day cycle). The 91 pills consist of 84 orange pills and 7 mustard pills. Blister strip 1 and 2 each contain 28 orange pills (4 rows of 7 pills). Blister strip 3 contains 35 pills consisting of 28 orange pills (4 rows of 7 pills) and 7 mustard pills (1 row of 7 pills).





3. Also find:

- Where on the first 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).

4. Be sure you have ready at all times another kind of birth control (such as condoms or spermicides), to use as a back-up in case you miss pills.

### When to Start Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets

1. Take the first orange pill on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the first orange pill that same day.

2. 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 orange pill until the next Sunday (first 7 days).

**If you are switching from another birth control method:**

If you have been using a different hormonal method of birth control (such as a different pill, the “patch,” or the “vaginal ring”), you need to use another method of birth control (such as condoms or spermicides) each time you have sex after stopping your old method of birth control until you have taken levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets for 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 and ethinyl estradiol tablets for 7 days.

**How to Take Levonorgestrel and Ethinyl Estradiol Tablets and Ethinyl Estradiol Tablets**

1. Take one pill at the same time every day until you have taken the last pill in the wallet.
  - Do not skip pills even if you are experiencing spotting or bleeding or feel sick to your stomach (nausea).
  - Do not skip pills even if you do not have sex very often.
2. When you finish a wallet
  - After taking the last mustard pill, start taking the first orange pill from a new Extended-Cycle Wallet the very next day (this should be on a Sunday) regardless of when your period started.
3. If you miss your scheduled period when you are taking the mustard pills, contact your healthcare provider because you may be pregnant. If you are pregnant, you should stop taking levonorgestrel and ethinyl estradiol tablets and ethinyl estradiol tablets.

**WHAT TO DO IF YOU MISS PILLS**

If you **MISS 1** orange pill:

1. 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.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** orange pills in a row:

1. Take 2 pills on the day you remember, and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You could become pregnant if you have sex in the **7 days** after you miss two pills. You **MUST** use another birth control method (such as condoms or spermicide) as a back up for the 7 days after you restart your pills.

If you **MISS 3 OR MORE** orange pills in a row:

1. Do not take the missed pills. Keep taking 1 pill every day as indicated on the pack until you have completed all of the remaining pills in the pack. For example: If you resume taking the pill on Thursday, take the pill under “Thursday” and do not take the missed pills. You may experience bleeding during the week following the missed pills.
2. You could become pregnant if you have sex during the days of missed pills or during the first **7 days** after restarting your pills.
3. You **MUST** use a non-hormonal birth control method (such as condoms 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 mustard pills, call your healthcare provider because you may be pregnant.

If you **MISS ANY** of the 7 mustard pills:

1. Throw away the missed pills.
2. Keep taking the scheduled pills until the pack is finished.
3. 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**

1. Use a back-up method anytime you have sex.
2. 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 has been approved by the U.S. Food and Drug Administration.

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