

Patient Information
Kurvelo™
(levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/30 mcg)

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

Do not use Kurvelo 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 is Kurvelo?

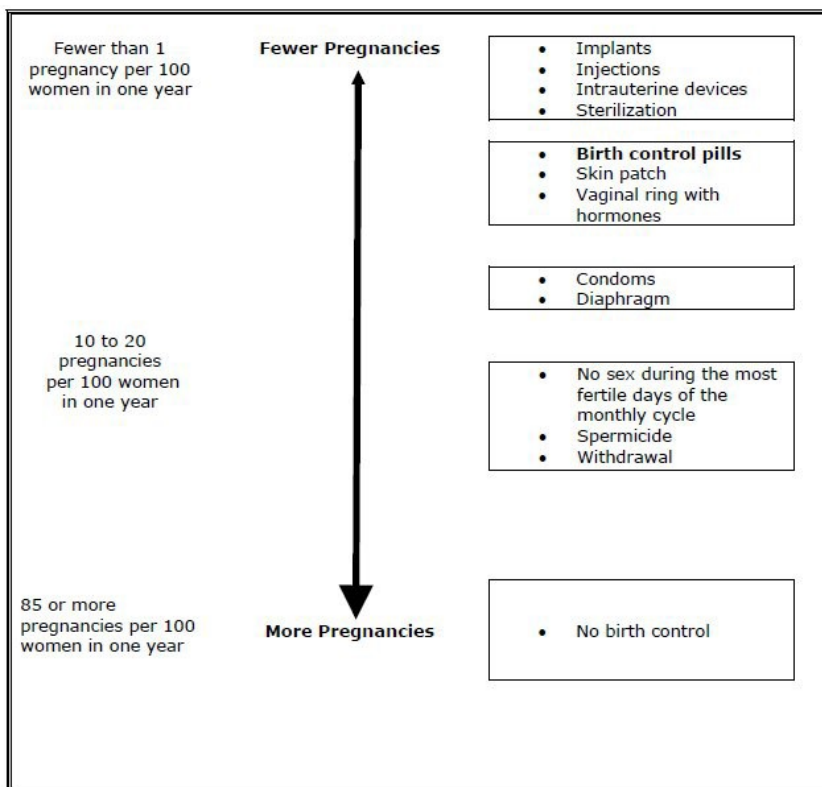
Kurvelo is a birth control pill (oral contraceptive) used by women to prevent pregnancy.

How does Kurvelo 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 Kurvelo.

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 Kurvelo? Do not take Kurvelo if you:

- smoke and are over 35 years of age
- had blood clots in your arms, legs, lungs, or eyes
- had a problem with your blood that makes it clot more than normal
- have certain heart valve problems or irregular heart beat
- 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
- had breast cancer or any cancer that is sensitive to female hormones
- have liver problems, including liver tumors
- have any unexplained vaginal bleeding
- are pregnant
- 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 Kurvelo, stop taking Kurvelo right away and talk to your healthcare provider. Use non-hormonal contraception when you stop taking Kurvelo.

What should I tell my healthcare provider before taking Kurvelo?**Tell your healthcare provider if you:**

- 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. Kurvelo may decrease the amount of breast milk you make. A small amount of the hormones in Kurvelo 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.

Kurvelo may affect the way other medicines work, and other medicines may affect how well Kurvelo 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 Kurvelo?

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

What are the possible serious side effects of Kurvelo?

- Like pregnancy, Kurvelo 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
- sudden severe shortness of breath
- a sudden, severe headache unlike your headaches
- sudden change in vision or away blindness
- chest pain
- 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 healthcare provider for a yearly check of your blood pressure.
- **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 Kurvelo.**
- **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 Kurvelo. Use sunscreen if you have to be in the sunlight.

What are the most common side effects of oral contraceptives?

- nausea
- vomiting
- bleeding between menstrual periods
- weight gain
- breast tenderness
- difficulty wearing contact lenses

These are not all the possible side effects of Kurvelo. For more information, ask your healthcare provider or pharmacist.

You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

What else should I know about taking Kurvelo?

- If you are scheduled for any lab tests, tell your healthcare provider you are taking Kurvelo. Certain blood tests may be affected by Kurvelo.
- Kurvelo does not protect against HIV-infection (AIDS) and other sexually transmitted infections.

How should I store Kurvelo?

- Store Kurvelo at room temperature between 68°F to 77°F (20°C to 25°C).
- Protect from light.

General information about the safe and effective use of Kurvelo.

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

This Patient Information Leaflet summarizes the most important information about Kurvelo. You can ask your pharmacist or healthcare provider for information about Kurvelo that is written for health professionals.

For more information, call Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

Does hormonal birth control cause cancer?

It is not known if hormonal birth control pills causes 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.

There may be slight increases in the risk of breast cancer among current users of hormonal birth control pills with longer duration of use of 8 years or more.

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 Kurvelo?

Your periods may be lighter and shorter than usual. Some women may miss a period. Irregular vaginal bleeding or spotting may happen while you are taking Kurvelo, especially during the first few months of use. This usually is not a serious problem. It is important to continue taking your pills on a regular schedule to prevent a pregnancy.

What are the ingredients in Kurvelo?

Active ingredients: Each light-orange pill contains levonorgestrel and ethinyl estradiol.

Inactive ingredients:

Light-orange pills: croscarmellose sodium, FD&C Yellow #6, lactose monohydrate,

magnesium stearate, microcrystalline cellulose and povidone.

Pink pills: croscarmellose sodium, D & C Red #30, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

Distributed by:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

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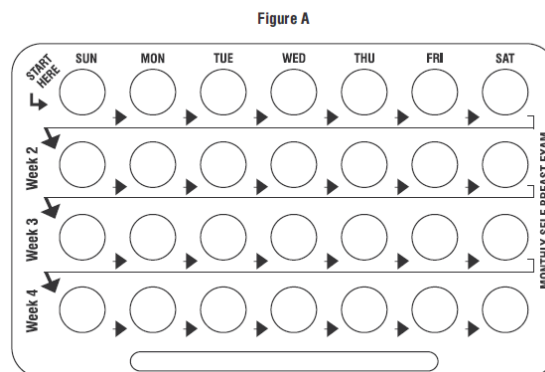
Instructions For Use Kurvelo™
(levonorgestrel and ethinyl estradiol tablets USP, 0.15 mg/30 mcg)

Important Information about taking Kurvelo

- Take **1** pill every day at the same time. Take the pills in the order directed on your pill pack.
- 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 Kurvelo, talk to your healthcare provider.
- When you first start taking Kurvelo, 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 Kurvelo. 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 Kurvelo 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 Kurvelo 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 Kurvelo.
- If you have vomiting or diarrhea within **3 to 4** hours of taking a light-orange pill, take another light-orange pill as soon as possible. Continue taking all your remaining pills in order. Start the first pill of your next pill pack the day after finishing your current pill 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 spermicide, until you check with your healthcare provider.
- Stop taking Kurvelo 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 Kurvelo:

- 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 pill pack.
- Look at your pill pack. Your pill pack consists of 1 card that holds 28 individually sealed pills. The 28 pills consist of 21 light-orange pills (3 rows of 7 pills) and 7 pink pills (1 row of 7 pills). **See Figure A.**



- Also find:
 - Where on the card to start taking pills (upper left corner) and
 - In what order to take the pills (follow the weeks)

- 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 Kurvelo?

If you start taking Kurvelo 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 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 Kurvelo. You do not need back-up contraception if you use the Day 1 Start.

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

- Start your new Kurvelo 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 pill pack.

If you start taking Kurvelo and previously used a vaginal ring:

- Start using Kurvelo on the day you would have started the next ring.

If you start taking Kurvelo and previously used a transdermal patch:

- Start using Kurvelo on the day you would have started a new cycle (first patch application).

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

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

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

- Start taking Kurvelo 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 Kurvelo.

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 Kurvelo?**” above. Follow these instructions for either a **Sunday Start** or a **Day 1 Start**.

Instructions for using your Kurvelo Pill Dispenser: Sunday Start:

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

- Take pill **1** on the Sunday **after your period starts**. To remove your pill from the dispenser, press the pill through the hole in the bottom of the dispenser.
- 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 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 (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 Kurvelo.

Day 1 Start:

You will use a **Day 1 Start** if your doctor told you to take your first pill (Day

1) on the **first day of your period**.

- Take 1 pill every day in the order of the pill dispenser, at the same time each day, for 28 days. To remove your pill from the dispenser, press the pill through the hole in the bottom of the dispenser.
- 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.

What should I do if I miss any Kurvelo 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.
 - 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 **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 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.
 - 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.

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

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