

**DRUG FACTS for XULANE® (norelgestromin and ethinyl estradiol transdermal system)**

Rx Product

**Active ingredients in the transdermal system**

Transdermal system: 150 mcg/day norelgestromin and 35 mcg/day ethinyl estradiol

**Purpose**

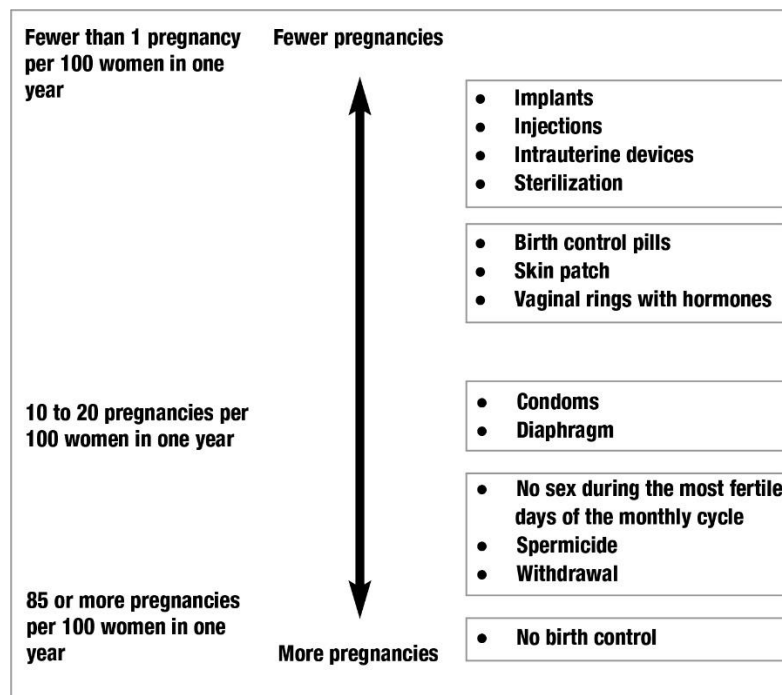
Prevention of pregnancy

**Uses:** XULANE is a prescription birth control patch for women with a BMI less than 30 kg/m<sup>2</sup>. It contains two female hormones, an estrogen called ethinyl estradiol, and a progestin called norelgestromin.

Hormones from XULANE get into the blood stream and are processed by the body differently than hormones from birth control pills. **You will be exposed to about 60% more estrogen if you use XULANE than if you use a typical birth control pill containing 35 micrograms of estrogen.** In general, increased estrogen may increase the risk of side effects.

XULANE may not be as effective in women weighing more than 198 lbs. (90 kg). If you weigh more than 198 lbs. (90 kg), talk to your healthcare provider about which method of birth control is right for you. Do not use XULANE if your Body Mass Index (BMI) is 30 kg/m<sup>2</sup> or more.

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, with the most effective methods at the top of the chart.

**Warnings**

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

**Do not use XULANE if you smoke cigarettes and are over 35 years old. Smoking increases your risk of serious cardiovascular side effects from hormonal birth control methods, including death from heart attack, blood clots or stroke. This risk increases with age and the number of cigarettes you smoke.**

**Do not use XULANE if you have an increased risk for blood clots.**

**Do not use XULANE if your Body Mass Index (BMI) is 30 kg/m<sup>2</sup> or more. Women with a BMI of 30 kg/m<sup>2</sup> or more who use Xulane may be at a higher risk for developing blood clots compared to women with a BMI lower than 30 kg/m<sup>2</sup>.**

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

Before using XULANE tell your doctor:

- If you are pregnant or think you are pregnant.
- If you are scheduled for surgery as Xulane may increase your risk of blood clots after surgery. You should stop using your Xulane patch at least 4 weeks before and through at least 2 weeks after surgery.
- If you are scheduled for any laboratory tests as certain blood tests may be affected by Xulane.

- If you have experienced yellowing of the skin or eyes caused by pregnancy or related to previous use of hormonal birth control.
- Are breastfeeding or plan to breastfeed. Xulane may decrease the amount of milk you make, and a small amount of hormones from the Xulane patch may pass into your breast milk.

Tell your healthcare professional about all medical conditions you may have and all medicines and herbal products that you take, including those for seizures and thyroid replacement therapy, as some may require dosing adjustments or may make Xulane less effective. Use another birth control method (such as a condom and spermicide or diaphragm and spermicide) when you take medicines that may make the Xulane patch less effective.

Some medicines and grapefruit juice may increase your level of the hormone ethinyl estradiol if used together with Xulane.

**Do not use XULANE if you:**

Smoke and are over 35 years old; have or have had blood clots; an inherited problem that makes your blood clot more than normal; history of heart attack, stroke, or certain heart valve or rhythm problems that can cause blood clots to form in the heart; high blood pressure that medicine cannot control; diabetes with kidney, eye, nerve, or blood vessel damage; certain kinds of severe migraine headaches with aura, numbness, weakness, or changes in vision or any migraine headaches if you are over 35; a BMI of 30 kg/m<sup>2</sup> or more; liver disease or liver tumors, if you take Hepatitis C drugs containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, as this may increase levels of the liver enzyme “alanine aminotransferase” (ALT) in the blood; have unexplained vaginal bleeding; have had breast cancer or any cancer that is sensitive to female hormones; or if you are or may be pregnant.

**When using XULANE, the following serious side effects may occur:**

Blood clots, especially if you have other risk factors, such as smoking, obesity, or age greater than 35. Some examples of blood clots are deep vein thrombosis (legs), pulmonary embolus (lungs), loss of eyesight (eyes), heart attack (heart), and stroke (brain). **These can cause death or lead to permanent disability.**

The risk of blood clots is highest when you first start using Xulane and when you restart Xulane or a different hormonal birth control after a break of a month or more. Some studies have reported that women who use norelgestromin and ethinyl estradiol transdermal system have a higher risk of getting a blood clot. Talk with your healthcare professional about your risk of getting a blood clot before using Xulane or deciding which type of birth control is right for you.

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

Leg pain that will not go away; sudden shortness of breath; sudden blindness, partial or complete; severe pain or pressure 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 eyeballs

**Other serious risks include:**

Liver problems including liver tumors; gallbladder disease; high blood pressure

**Common side effects:**

The most common side effects reported in at least 5% of women during clinical trials were breast symptoms (discomfort, swelling, or pain); nausea/vomiting; headache; skin irritation, redness, pain, swelling, itching or rash at the patch application site; stomach pain; pain during menstruation; vaginal bleeding and menstrual disorders, such as spotting or bleeding between periods; and mood, affect and anxiety disorders.

**Does hormonal birth control cause cancer?**

It is not known if hormonal birth control causes 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.

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

**Directions:** XULANE uses a 28-day (4-week) cycle. Apply a new patch to the upper outer arm, abdomen, buttock or back each week for 3 weeks (21 total days). Week 4 is a patch-free week.

Your chance of getting pregnant depends on how well you follow the directions for using XULANE. The better you follow the directions, the less chance you have of getting pregnant. In clinical studies, 1 to 2 out of 100 women got pregnant during the first year that they used norelgestromin and ethinyl estradiol transdermal system.

**Do not cut, damage, or alter the XULANE Patch in any way.**

**For detailed instructions, see the step-by-step in the instructions at the end of the Patient Information in the XULANE prescribing information.**

**Other information:** •For application to the skin only •store at room temperature 68-77° F (20-25° C) •Do not store XULANE Patches outside of their pouches. Apply immediately upon removal from the protective pouch •Do not store in the refrigerator or freezer •Used XULANE Patches still contain some active hormones. To throw away the XULANE Patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash. Do not flush XULANE down the toilet •Return unused, unneeded, or expired patches to your pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088**

**Inactive Ingredients:** •polyethylene •polyester •polyisobutene adhesive •crospovidone •mineral oil •non-woven polyester fabric •oleyl alcohol •dipropylene glycol •a polyester film with a fluoropolymer coating.

**The risk information provided here is not comprehensive.** To learn more, talk about XULANE with your healthcare provider or pharmacist. The FDA-approved product label can be found at [DailyMed - XULANE- norelgestromin and ethinyl estradiol patch](#) or call 1-877-446-3679

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