

This tool should not be considered inclusive of all important factors influencing a choice of birth control method. Be sure to discuss the risks and benefits of all your options with your healthcare provider and remember that it's important to be honest with your doctor about your lifestyle choices, including whether you smoke.

Current Lifestyle Questions & Considerations For You

- Are you looking to start or seek a birth control method?
- Are you looking for hormonal or non-hormonal birth control methods?
- Do you want to have children and when?

Birth Control Methods Questions & Considerations For Your Doctor

- Can you tell me a little about the short-term and long-term birth control methods?
- What birth control options do you recommend for me and why?
- Can you tell me about the different ways to apply or take birth control? What are all my options?

XULANE Questions & Considerations For Your Doctor

- When considering my individual medical history and lifestyle, is XULANE appropriate for me?
- What are the possible side effects of XULANE?
- I'm currently on another method. How do I change to XULANE?

Indication and Usage

What is XULANE?

XULANE is a prescription birth control patch for women with a BMI less than 30 kg/m². 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.

Limitation of Use:

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/m² or more.

IMPORTANT SAFETY INFORMATION

Boxed WARNING

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/m² or more. Women with a BMI of 30 kg/m² 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/m².

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

Who should not use XULANE?

Do not use XULANE if you 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/m² or more; liver disease or liver tumors; unexplained vaginal bleeding; have had breast cancer or any cancer that is sensitive to female hormones; 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; or if you are or may be pregnant.

Before you use XULANE:

Tell your healthcare professional about all of your medical conditions, including:

- 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 medicines and herbal products that you take, including those for seizures and thyroid replacement therapy, as some of these 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.

See next page for additional Important Safety Information.

IMPORTANT SAFETY INFORMATION (con't)

What are the most serious risks of taking XULANE?

XULANE may cause serious side effects, including 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

What are the most common side effects of XULANE?

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.

Tell your healthcare professional about any side effect that bothers you or that does not go away. These are not all the possible side effects of XULANE. For more information, ask your healthcare professional or pharmacist. **Call your healthcare provider for medical advice about side effects.**

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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.

This is not all of the information you should read prior to using XULANE. Click here for [Patient Information](#) and [Full Prescribing Information](#), including **Boxed WARNING**.

Talk to your healthcare provider if you have any questions about using XULANE patch.