

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.

## Current Lifestyle Questions & Considerations For You

- Are you looking to start or seek other birth control methods?
- 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?
- I'm unsure if I want birth control inserted in my body. What are all my options?

## Xulane Questions & Considerations

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

## Indication and Usage

### What is Xulane?

Xulane® is a prescription birth control patch used for the prevention of pregnancy in women who choose to use a transdermal patch.

### 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 professional about which method of birth control is right for you

**Hormonal birth control methods help to lower the chances of becoming pregnant. They do not protect against HIV infection (AIDS) and other sexually transmitted infections.**

## 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.**

**Women 15 to 44 years of age who use Xulane may have an increased risk of blood clots compared to women who use certain 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, including blood clots.**

## Important Safety Information (con't)

### Who should not use Xulane?

#### Do not use Xulane if you:

- Smoke and are over 35 years old
- Have or have had blood clots in your arms, legs, eyes or lungs
- Have an inherited problem that makes your blood clot more than normal
- Have had a stroke
- Have had a heart attack
- Have certain heart valve problems or heart rhythm problems that can cause blood clots to form in the heart
- Have high blood pressure that medicine cannot control
- Have diabetes with kidney, eye, nerve, or blood vessel damage
- Have had certain kinds of severe migraine headaches with aura, numbness, weakness or changes in vision, or have any migraine headaches if you are over age 35
- Have liver disease, including liver tumors (benign or cancerous)
- 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.
- Have unexplained vaginal bleeding
- Are pregnant or think you may be pregnant.
- However, Xulane is not known to cause birth defects when used by accident during pregnancy.
- Have had breast cancer or any cancer that is sensitive to female hormones

Hormonal birth control methods may not be a good choice for you if you have ever had jaundice (yellowing of the skin or eyes) caused by pregnancy or related to previous use of hormonal birth control.

Tell your healthcare professional if you have ever had any of the above conditions. Your healthcare professional may recommend another method of birth control.

### Before you use Xulane tell your healthcare professional:

- About all your medical conditions.
- If you are pregnant or think you are pregnant.
- If you are scheduled for surgery. Xulane may increase your risk of blood clots after surgery. You should stop using your Xulane patch at least 4 weeks before you have surgery and not restart it until at least 2 weeks after your surgery.
- If you are or will be inactive or immobilized for a long period of time.
- If you are scheduled for any laboratory tests. Certain blood tests may be affected by hormonal birth control methods.
- Are breastfeeding or plan to breastfeed. Hormonal birth control methods that contain estrogen, like Xulane, may decrease the amount of milk you make. A small amount of hormones from the Xulane patch may pass into your breast milk. Consider another method of birth control until you are ready to stop breastfeeding.

Tell your healthcare professional about all medicines and herbal products that you take.

Some medicines and herbal products may make hormonal birth control less effective, including, but not limited to:

- certain seizure medicines (carbamazepine, felbamate, oxcarbazepine, phenytoin, rufinamide, and topiramate)
- aprepitant
- barbiturates
- bosentan
- griseofulvin
- certain combinations of HIV medicines (nelfinavir, ritonavir, ritonavir-boosted protease inhibitors)
- certain non-nucleoside reverse transcriptase inhibitors (nevirapine)
- rifampin and rifabutin
- St. John's wort

## Important Safety Information (con't)

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, including:

- acetaminophen
- ascorbic acid
- medicines that affect how your liver breaks down other medicines (itraconazole, ketoconazole, voriconazole, and fluconazole)
- certain HIV medicines (atazanavir, indinavir)
- atorvastatin
- rosuvastatin
- etravirine

Hormonal birth control methods may interact with lamotrigine, an anti-seizure medicine used for epilepsy. This may increase the risk of seizures, so your healthcare professional may need to adjust the dose of lamotrigine.

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

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

### **What are the possible side effects of Xulane?**

**Xulane may cause serious side effects, including:**

- **Blood clots.**

Like pregnancy, hormonal birth control methods increase the risk of serious blood clots, especially in women who have other risk factors, such as smoking, obesity, or age greater than 35. This increased risk is highest when you first start using hormonal birth control and when you restart the same or different hormonal birth control after not using it for 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.

**It is possible to die or be permanently disabled 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 (deep vein thrombosis)
- lungs (pulmonary embolus)
- eyes (loss of eyesight)
- heart (heart attack)
- brain (stroke)

**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

### Important Safety Information (con't)

**Other serious risks include:**

- liver problems including liver tumors
- gallbladder disease
- high blood pressure

**The most common side effects of Xulane are:**

- breast symptoms (discomfort, swelling, or pain)
- nausea
- 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
- mood, affect and anxiety disorders

Some women have spotting or light bleeding, breast tenderness, or feel sick to their stomach during norelgestromin and ethinyl estradiol transdermal system use. If these symptoms occur, do not stop using the Xulane patch. The problem will usually go away. If it doesn't go away, check with your healthcare professional. Less common side effects are:

- acne
- less sexual desire
- bloating or fluid retention
- blotchy darkening of your skin, especially your face
- high blood sugar, especially in women with diabetes
- high fat (cholesterol, triglycerides) levels in the blood
- depression, especially if you have had depression in the past. Call your healthcare professional immediately if you have any thoughts of harming yourself.
- problems tolerating contact lenses
- weight gain

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.

### Important Safety Information (con't)

#### **What should I know about my period when using Xulane?**

- When you use Xulane, you may have bleeding and spotting between periods called unplanned bleeding. Such bleeding may be temporary and usually does not indicate any serious problems. It is important to continue using the patch on schedule. If the unplanned bleeding or spotting is heavy or lasts for more than a few days, you should discuss this with your healthcare professional.

#### **What if I miss my scheduled period when using Xulane?**

- Some women miss periods on hormonal birth control, even when they are not pregnant. However, if you go 2 or more months in a row without a period, or you miss your period after a month where you did not use all of your patches correctly, or you have symptoms associated with pregnancy, such as morning sickness or unusual breast tenderness, call your healthcare professional because you may be pregnant. Stop taking Xulane if you are pregnant.

#### **How do I use Xulane after childbirth?**

- If you are not breastfeeding, wait 4 weeks before using Xulane and use a non-hormonal contraceptive method of birth control, such as a condom and spermicide or diaphragm and spermicide, for the first 7 days of your first cycle only. If you have had sex since your baby was born, wait for your first period, or see your healthcare provider to make sure you are not pregnant before starting Xulane.

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

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call **1-800-FDA-1088** .

**This is not all of the information you should read prior to using Xulane. Please see accompanying Full Prescribing Information, including Boxed WARNING.**