

# Xulane<sup>®</sup>

(norelgestromin and ethinyl estradiol transdermal system)  
150/35 mcg per day

## Learn about a weekly birth control patch.

Xulane is applied 1 time each week for 3 weeks. Week 4 is patch-free.

Check your patch every day to make sure all edges are sticking correctly.

For women with a body mass index (BMI) of less than 30 kg/m<sup>2</sup>.



Scan the code to learn more about Xulane.



Not an actual patient. Patch is an artistic rendition shown to scale.

### What is XULANE?

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.

**Limitations 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/m<sup>2</sup> 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/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.**

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

# Meet the Xulane Patch

## Looking for a different birth control option?

Get to know Xulane (zoo-lane) — it's a prescription birth control patch for women with a BMI less than 30 kg/m<sup>2</sup>

XULANE is a weekly birth control patch that's applied to either your upper outer arm, abdomen, buttock, or back in a place where it won't be rubbed by tight clothing. XULANE patch is applied in a 4-week cycle. You apply a patch 1 time each week for 3 weeks. Week 4 is your patch-free week when your period is expected. **Your XULANE patch must stick securely to your skin to work properly, so remember to check your patch every day to make sure it's sticking correctly.** In clinical studies with NGMN/EE, approximately 2% of patches completely detached and 3% partially detached. Talk to your healthcare provider if you have any questions on using XULANE patch. Your chance of getting pregnant depends on how well you follow the directions for using XULANE. In clinical studies of a similar product containing NGMN/EE, 1 to 2 out of 100 women got pregnant during the first year they used NGMN/EE patch as directed. XULANE may not be as effective in preventing pregnancy in women who weigh 198 lbs. (90 kg) or more. 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 BMI is 30 kg/m<sup>2</sup> or more.**

This is not a full list of the reasons why XULANE may not be right for you. For more information, see the "Who should not use Xulane?" discussion below in the pink bar.

Hormonal birth control methods, such as XULANE, help to lower the chances of getting pregnant. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

**NGMN:** Norelgestromin. **EE:** Ethinyl estradiol.

### IMPORTANT SAFETY INFORMATION (Continued)

**Limitations 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/m<sup>2</sup> or more.

#### 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;

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

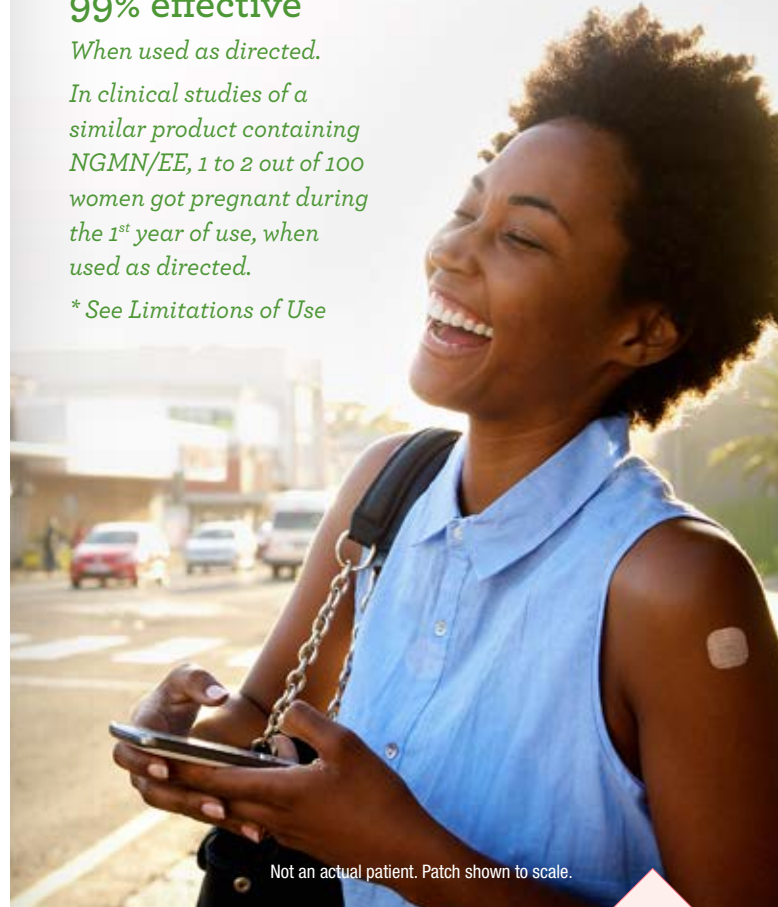
**Xulane**<sup>®</sup>  
(norelgestromin and ethinyl  
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150/35 mcg per day

**99% effective\***

*When used as directed.*

*In clinical studies of a similar product containing NGMN/EE, 1 to 2 out of 100 women got pregnant during the 1<sup>st</sup> year of use, when used as directed.*

*\* See Limitations of Use*



Not an actual patient. Patch shown to scale.

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 or more; liver disease or liver tumors; unexplained vaginal bleeding; 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.

# Size up Xulane

## Xulane Patch may be smaller than you think

At just 1.5" x 1.5", it's just a little larger than a quarter. And you have 4 choices on where to wear it, so you can choose to place it under your clothing. See pages 6-7 on where to apply Xulane.



For more  
information

Xulane.com

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### IMPORTANT SAFETY INFORMATION (Continued)

#### 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.

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

- 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 adjustment or 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.

# Where does the Xulane patch go?

Xulane can be placed on your upper outer arm, abdomen, buttock or back in a place where it won't be rubbed by tight clothing. **Do not** place on your breasts or on the same skin area as the previous patch. Only apply to clean, dry skin. **Do not** use lotions, creams, oils, powders, or makeup at the patch site. Check the patch every day to make sure all edges are sticking correctly. **Your patch must stick securely to your skin to work properly.** Do not try to reapply a patch if it is no longer sticky. Do not tape or wrap the patch to your skin.



For detailed instructions, see the step-by-step instructions for using Xulane in the Patient Information section of the accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

[Visit Xulane.com](https://www.xulane.com)

\* Patch is an artistic rendition shown to scale.

## IMPORTANT SAFETY INFORMATION (Continued)

### 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.

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Not an actual patient.

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](https://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 the accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

# 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 NGMN/EE 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.

These are not all the risks of taking Xulane. Please review pages 20-21 of this brochure for additional Xulane safety information and talk to your healthcare provider about the benefits and risks of taking Xulane.

NGMN: Norelgestromin. EE: Ethinyl estradiol.

## IMPORTANT SAFETY INFORMATION (Continued)

### 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

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Actor Portrayal.

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.


## Am I a patch match?\*


Xulane is not for everyone. You should discuss your individual medical history, health risks and lifestyle choices with your healthcare provider to determine whether the Xulane Patch may be a match for you.

### Know what you want from your birth control?

#### I WANT TO

 Help prevent pregnancy at this stage in my life

 Explore my birth control options

 Keep my family planning options open

\* The above factors are not the only factors to consider in determining whether the Xulane Patch may be appropriate for your particular birth control needs. Be sure to discuss the risks and benefits of all your options with your healthcare provider.

#### IMPORTANT SAFETY INFORMATION (Continued)

**Limitations 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/m<sup>2</sup> or more.

#### 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;

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### Do not use Xulane if you are or may be pregnant, or have

- Or have had blood clots
- An inherited problem that makes your blood clot more than normal
- A 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 or more
- Liver disease or liver tumors
- Unexplained vaginal bleeding;
- 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

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 or more; liver disease or liver tumors; unexplained vaginal bleeding; 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.

# How do I start Xulane?

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If you are not currently using hormonal birth control, there are two options for starting the patch. Choose the option that is right for you:

## First day start

Apply your first patch during the first 24 hours of your menstrual period.

## Sunday start

Apply your first patch on the first Sunday after your menstrual period begins. 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 your period starts on Sunday, apply your first patch that day, and no backup birth control is needed.

## If you are changing from the pill or vaginal contraceptive ring to the patch

Complete your current pill cycle or vaginal ring cycle. Apply your first patch on the day you would normally start your next pill or insert your next vaginal ring. If you do not get your period within one week after taking your last active pill or removing your last vaginal ring, check with your healthcare provider to make sure you are not pregnant. You may still go ahead and start the patch for contraception. If you apply your patch more than one week after taking your last active pill or removing your last vaginal ring, use a non-hormonal contraceptive method with the patch for the first 7 days of patch use.

## IMPORTANT SAFETY INFORMATION (Continued)

### 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.

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

## If you are starting after childbirth

If you are not breastfeeding, wait 4 weeks before using the patch 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 the patch.

## If using after abortion or miscarriage

You may start the patch immediately after a miscarriage or abortion that occurs in the first 12 weeks (first trimester) of pregnancy. You do not need to use another contraceptive method.

If you do not start the patch within 5 days after a first trimester miscarriage or abortion, use a non-hormonal contraceptive method of birth control, such as a condom and spermicide or diaphragm and spermicide, while you wait for your period to start. You should follow the instructions on the left for first day start or Sunday start based on what's right for you, and read the full Patient Information for starting Xulane.

If you are starting the patch after a miscarriage or abortion that occurs after the first 12 weeks of pregnancy (second trimester), wait 4 weeks before using the patch 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 miscarriage or abortion, wait for your first period, or see your healthcare provider to make sure you are not pregnant before starting the patch.

- 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 adjustment or 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.

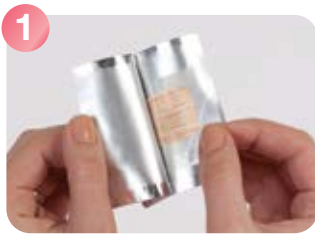
# Get ready to apply Xulane

Use Xulane exactly as your healthcare provider tells you to use it. Place the patch on your upper outer arm, abdomen, buttock or back in a place where it won't be rubbed by tight clothing. For example, you should not place it under the waistband of clothing. **Do not** place on your breasts, cut or irritated skin, or the same location as your last patch. Do not cut, damage, or alter the Xulane Patch in any way.

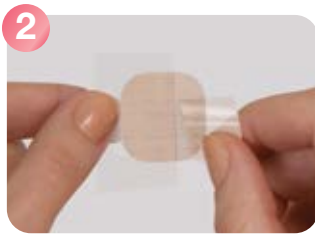
## Before applying

**Make sure your skin is clean and dry. Don't use lotions, creams, oils, powders, or makeup at the patch site. This may cause the patch to fail to stick properly or become loose.**

## Applying Xulane



Tear open the pouch at the top edge and one side edge. Peel open the foil pouch and gently remove the contents of the foil pouch and discard the additional pieces of film above and below the patch.



Peel away half of the clear plastic. Avoid touching the sticky surface with your fingers.

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Apply the sticky side of the patch on your clean, dry skin. Remove the other half of the clear plastic and attach the entire patch to your skin.

**Check your patch every day to make sure all edges are sticking correctly.**

[Visit Xulane.com](https://www.xulane.com)



**Press firmly on the patch with the palm of your hand for 10 seconds**, making sure that the whole patch sticks to your skin. Run your fingers over the entire surface area to smooth out any “wrinkles” around the outer edges of the patch.

**Your XULANE patch must stick securely to your skin to work properly.**

## How should I use Xulane

Wear one Xulane Patch at a time. Make sure you remove your old patch before applying your new patch. **Do not** skip using any patches, even if you do not have

sex often. Xulane is applied in a 4-week cycle.

Please see page 18 for more information on how to use Xulane.

## IMPORTANT SAFETY INFORMATION (Continued)

### 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.

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.



## How should I use Xulane (continued)


- Apply your patch one time each week for 3 weeks (21 total days).
- Apply each new patch on the same day of the week. This day will be your “Patch Change Day”. For example, if you apply your first patch on a Monday, all of your patches should be applied on a Monday.
- Do not apply your patch during week 4. Make sure you remove your old patch. This is your patch-free week. Your menstrual period should start during your patch-free week.
- Begin a new 4-week cycle by applying a new patch on the day after week 4 ends. Repeat the cycle of 3 weekly applications followed by a patch-free week.
- Your patch should never be off for more than 7 days in a row. If your patch is off for more than 7 days in a row and you have sex during this time, you could become pregnant.
- If you miss a period you might be pregnant. Some women miss their periods or have light periods on hormonal birth control methods even when they are not pregnant. Call your healthcare provider if you miss one period and have not used your patch every day or you miss two periods in a row.

If your Xulane Patch becomes uncomfortable or your application site is red, painful, or swollen, remove your patch and apply a new patch to a new location until your next “Patch Change Day”.

To throw away the Xulane Patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place the container in the trash. Used Xulane patches should not be flushed in the toilet.

Store at room temperature between 20 to 25 degrees C (68-77 degrees F). Do not store in the refrigerator or freezer.

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*For information about what to do if your Xulane patch edges lift up or your Xulane patch becomes partially or fully detached, please read the Patient Information in the accompanying Consumer Brief Summary of Information.*

Not an actual patient. Patch shown to scale.

### IMPORTANT SAFETY INFORMATION (Continued)

#### 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.

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

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](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 the accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

# Switching from another contraceptive method to Xulane Patch

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## Oral combination hormonal contraception (oral CHC)

- If the woman is switching from the pill to Xulane, she should complete her current pill cycle and apply the first Xulane patch on the day she would normally start her next pill
- If she does not get her period within a week after taking the last active pill, she should check with her healthcare professional to be sure that she is not pregnant, but she may go ahead and start Xulane for contraception.
- If the patch is applied more than a week after taking the last active pill, she should use a non-hormonal back-up contraception (such as condoms and spermicide, or diaphragm and spermicide) concurrently for the first 7 days of patch use.

## Transdermal system

- If the woman is switching from another contraceptive transdermal system to Xulane, she should complete the current transdermal system cycle and apply the first Xulane patch on the day the next transdermal system cycle would normally start.
- If she does not get her period within a week after removing the last transdermal system, she should check with her healthcare professional to be sure that she is not pregnant, but she may go ahead and start Xulane for contraception.

If Xulane is applied more than a week after removal of the last patch, nonhormonal back-up contraception (such as condoms and spermicide, or diaphragm and spermicide) should be used concurrently for the first 7 days of patch use.

## Vaginal ring

- If the woman is switching from the vaginal ring to Xulane, she should complete her current vaginal ring cycle and apply the first Xulane patch on the day she would normally insert her next vaginal ring.
- If she does not get her period within a week after removing the last vaginal ring, she should check with her healthcare professional to be sure that she is not pregnant, but she may go ahead and start Xulane for contraception.
- If the patch is applied more than a week after removal of the last vaginal ring, she should use a non-hormonal back-up contraception (such as condoms and spermicide, or diaphragm and spermicide) concurrently for the first 7 days of patch use.

## Intrauterine system (IUS)

- If the woman is switching from an injection contraceptive to Xulane, she should apply the first Xulane patch on the day the next injection would normally occur.

## Injection

- If the woman is switching from an intrauterine system to Xulane, she should apply the first Xulane patch on the day of IUS removal.

## Implant

- If the woman is switching from an implant to Xulane, she should apply the first Xulane patch on the day of implant removal.

## Progestin-only pill

- If the woman is switching from a progestin-only pill to Xulane, she should apply the first Xulane patch on the day the next progestin-only pill cycle would normally start.

## IMPORTANT SAFETY INFORMATION (Continued)

**Limitations 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/m<sup>2</sup> or more.

### 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 or more; liver disease or liver tumors; unexplained vaginal bleeding; 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.

Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

## IMPORTANT SAFETY INFORMATION

### What is XULANE?

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.

### Limitations 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/m<sup>2</sup> 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/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.**

### 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 or more; liver disease or liver tumors; unexplained vaginal bleeding; 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 adjustment 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.

### 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](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 Consumer Brief Summary of Information, including **Boxed WARNING**.



**Xulane®**  
(norelgestromin and ethinyl  
estradiol transdermal system)  
150/35 mcg per day

Not an actual patient.



Actual size is 1.5" x 1.5"

## Ask about Xulane birth control patch

For more  
information } [Xulane.com](https://www.xulane.com)

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Please see accompanying Consumer Brief Summary of Information, including **Boxed WARNING**.

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