

Xulane®

(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/m².

See additional *Limitations of Use* below.



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/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.

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/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.

Please see full Important Safety Information on pages 20 and 21 and 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/m²

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 of a similar product containing 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/m² 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.¹

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/m² 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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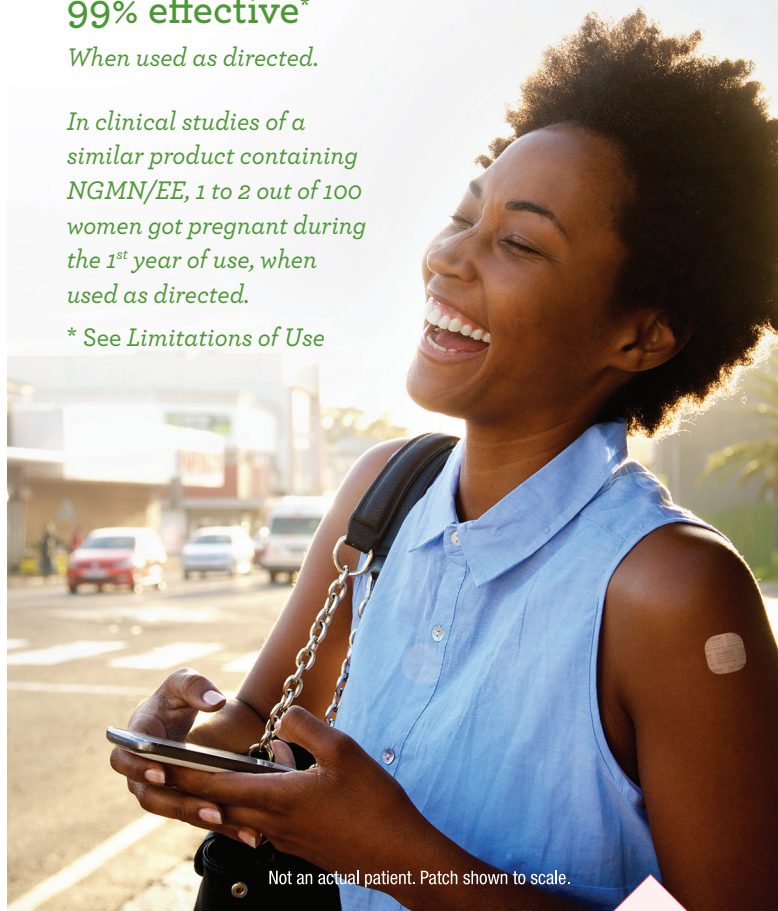
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99% effective*

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 1st 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 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.

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.¹ See pages 6-7 on where to apply XULANE.



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

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.

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- 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. Check the patch every day to make sure all edges are sticking correctly. Only apply to clean, dry skin. **Your patch must stick securely to your skin to work properly.** Do not place on your breasts, on cut or irritated skin, or on the same skin area as the previous patch. Do not use lotions, creams, oils, powders, or makeup at the patch site. Do not try to reapply a patch if it is no longer sticky. Do not tape or wrap the patch to your skin.¹



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.

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**

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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. Please see 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.¹

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.¹

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/m² 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 smoke and are over 35 years old, or you:

- have or have had blood clots
- have an inherited problem that makes your blood clot more than normal
- have a history of heart attack, stroke, or certain heart valve or 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 any migraine headaches if you are over age 35
- have a BMI of 30 kg/m² or more
- have liver disease or liver tumors
- have unexplained vaginal bleeding;
- are pregnant or think you may be pregnant
- 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

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.

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 birth control. 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 birth control method with the patch for the first 7 days of patch use.

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 birth control 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.¹

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 full Important Safety Information on pages 20 and 21 and 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.

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.¹

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.



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.

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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 XULANE patches, even if

you do not have sex often. XULANE is applied in a 4-week cycle.

Please see page 16 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.

Please see full Important Safety Information on pages 20 and 21 and 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°C (68° to 77°F). Do not store in the refrigerator or freezer.¹

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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)

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.

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Switching from another birth control method to XULANE Patch

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Oral combination hormonal birth control pill

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

Birth control patch

- If you are switching from another birth control patch to XULANE, you should complete the current patch cycle and apply the first XULANE patch on the day the next patch cycle would normally start.
- If you do not get your period within a week after removing the last patch, you should check with your healthcare professional to be sure that you are not pregnant, but you may go ahead and start XULANE for birth control.
- If XULANE is applied more than a week after removal of the last patch, non-hormonal back-up birth control (such as condoms and spermicide, or diaphragm and spermicide) should be used as well as XULANE for the first 7 days of patch use.

Vaginal ring

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

Intrauterine system (IUS)

- If you are switching from an intrauterine system to XULANE, you should apply the first XULANE patch on the day of IUS removal.
- If the IUS is not removed on the first day of your menstrual cycle, you should use non-hormonal backup birth control (such as condoms and spermicide, or diaphragm and spermicide) as well as XULANE for the first 7 days of patch use.

Injection

- If you are switching from an injection birth control to XULANE, you should apply the first XULANE patch on the day the next injection would normally occur.

Implant

- If you are switching from an implant to XULANE, you should apply the first XULANE patch on the day of implant removal.

Progestin-only pill

- If you are switching from a progestin-only pill to XULANE, you should apply the first XULANE patch on the day the next progestin-only pill cycle would normally start.

IMPORTANT SAFETY INFORMATION (Continued)

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

Please see full Important Safety Information on pages 20 and 21 and 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/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.

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

Our XULANE Savings Card Program

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

Save up to \$100 for the first prescription fill of Xulane®*

and up to \$25 after you pay the first \$15 for each subsequent prescription fill

*Eligibility restrictions apply. See full Terms and Conditions below. Not valid for patients enrolled in federal or state healthcare programs, such as Medicare, Medicaid, or TRICARE, and not valid for uninsured patients (but may be used by commercially insured patients without coverage for Xulane®). Mylan Pharmaceuticals Inc., a Viatris Company, reserves the right to amend or end this program at any time without notice.

RxBIN: 610524

RxPCN: Loyalty

RxGRP: 50777450

ISSUER: 80640

ID: <XXXXXXXXXX>



This savings card is not available to uninsured patients or patients who are covered by a state or federally funded healthcare program.

See full Terms and Conditions.



What is the XULANE Savings Card?

It's a savings offer that may be able to reduce your out-of-pocket costs on XULANE prescriptions to **as little as \$0** on your first prescription fill and \$15 on each subsequent prescription fill.



Eligible patients who have commercial health insurance **may receive up to \$100 off** the first 28-day prescription fill of XULANE. For subsequent fills, eligible patients who have commercial health insurance, and **pay \$15 on each subsequent fill, may receive up to \$25 off** each 28-day prescription fill of XULANE, up to an aggregate maximum of **\$425 per calendar year**.



You can print the savings offer from your computer or store it on your smartphone and present it to your pharmacist. Just present your card at the pharmacy each time you drop off or refill your prescription.

XULANE® (norelgestromin and ethinyl estradiol transdermal system) 150/35 mcg per day Savings Card Terms and Conditions

This Savings Card may be used to reduce the amount of your out-of-pocket costs for XULANE® (norelgestromin and ethinyl estradiol transdermal system) 150/35 mcg per day up to a maximum of \$100 per 28-day prescription for the first fill, and then for subsequent fills, up to a maximum of \$25 per 28-day prescription after you pay the first \$15 per 28-day prescription, while this program remains in effect. No other purchase is necessary. This offer can be used up to a total of 14 times per calendar year, with an aggregate savings cap of \$425 per calendar year while this program remains in effect. Valid prescription with Prescriber ID# is required. Mylan Pharmaceuticals Inc., a Viatris Company, reserves the right to amend or end this program at any time without notice.

Eligibility Requirements: This Savings Card can be redeemed only by patients or patient guardians who are 18 years of age or older and who are residents of the United States and its territories. Patients must have commercial insurance. This program is not valid for uninsured patients (but may be used by commercially insured patients without coverage for XULANE) and patients who are covered by any state or federally funded healthcare program, including

but not limited to any state pharmaceutical assistance program, Medicare (Part D or otherwise), Medicaid, Medigap, VA or DOD, or TRICARE (regardless of whether XULANE is covered by such government program); not valid if the patient is Medicare eligible and enrolled in an employer-sponsored health plan or prescription benefit program for retirees; and not valid if the patient's insurance plan is paying the entire cost of this prescription. This program is void outside the US and its territories or where prohibited by law, taxed, or restricted. Absent a change in Massachusetts law, this program will no longer be valid for Massachusetts residents after January 1, 2023. This program is not valid for residents of California.

This Savings Card is not health insurance. This Savings Card is not transferable, and the amount of the savings cannot exceed the patient's out-of-pocket costs. This program cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. This Savings Card is not redeemable for cash.

NOTICE: Data related to your use of this Savings Card may be collected, analyzed and shared with Mylan Pharmaceuticals Inc. for market research and other purposes related to assessing coupon programs. Data shared with Mylan Pharmaceuticals Inc. will be aggregated and de-identified, meaning it will be combined with data related to other savings card redemptions and will not identify you.

Patient Instructions: By using this Savings Card, you acknowledge that you currently meet the eligibility criteria and that you understand and will comply with the following additional terms and conditions:

- You have not submitted and will not submit a claim for reimbursement under any federal, state or other governmental programs for this prescription.
- Your use of this Savings Card must be consistent with the terms of any drug benefit provided by your commercial health insurer, health plan, or private third-party payer. You agree to report the use of this Savings Card to your commercial insurer if required.
- Where required, a Savings Card and prescription drug insurance card, along with a valid prescription for XULANE, must be presented to your pharmacist.

Pharmacist Instructions: When you accept this Savings Card, you are certifying that you have received this Savings Card from an eligible patient; you have received a valid prescription for XULANE for an eligible patient; you have dispensed the product as indicated; you have not submitted and will not submit a claim for reimbursement under any federal, state or other governmental programs for this prescription; and you will otherwise comply with these terms and all applicable terms and conditions. You further certify that your participation in this program is consistent with all applicable state laws and any obligations, contractual or otherwise, that you have as a pharmacy provider, and that you will report the use of this Savings Card to the patient's insurer if required.

- Submit transaction to McKesson Corporation using BIN #610524.
- For commercially insured patients, input this Savings Card information as secondary coverage and transmit using the COB segment of the NCPDP transaction. Applicable patient savings will be displayed in the transaction response.
- Acceptance of this Savings Card and your submission of claims for the XULANE® Savings Card program are subject to the Savings Card Terms and Conditions posted at www.activatecard.com/viatrisadvocate/xulane/welcome#nc.
- Acceptance of this Savings Card and your submission of claims for the XULANE® Savings Card program are subject to the LoyaltyScript® program Terms and Conditions posted at www.mckesson.com/mprstnc.
- For questions regarding setup, claim transmission, patient eligibility or other issues, call the LoyaltyScript® for the XULANE® Savings Card program at 800-657-7613 (8:00 AM-8:00 PM EST, Monday-Friday).

Please see full Important Safety Information on pages 20 and 21 and accompanying [Consumer Brief Summary of Information](#), including **Boxed WARNING**.

Xulane®

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

Ask your doctor to indicate “DAW”

(Dispense As Written)*
or the language used in your state
(as appropriate) on all of your
XULANE prescriptions so you know
you're receiving the same XULANE
patch you've been prescribed—patch
to patch, month to month.

Some pharmacies can fill your XULANE
prescription with a different generic and
may not be required to notify you.

**Check your bag before leaving the pharmacy to be sure
you're receiving XULANE.** If you think your prescription has
been changed, please speak with your pharmacist. You may be
able to get the XULANE patch as your doctor prescribed.



**You may be able to get 3 months of XULANE at one time
with a year's worth of refills. Ask your doctor to prescribe
9 patches with 3 refills.†**

Nationally, nearly **91%** of all filled XULANE prescriptions
for patients with commercial insurance had a **\$0** patient
out-of-pocket costs after insurance for the 12 months
ending 11/30/21‡

* Language and requirements may vary based on your state's law.

† Formularies vary and are subject to change without notice; please check directly with the plan to
determine the most current information. This is not a guarantee of coverage or payment (full or partial);
state of residency may impact coverage and dispensing.

‡ It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and
claim submission guidance with the patient's health insurance plan to ensure XULANE claims are
accurate, complete, and supported by documentation in the patient's medical record. Allowable ICD-10
codes may vary by payer. VIATRIS™ does not guarantee that payers will consider all codes appropriate
for all encounter scenarios and Viatrix does not guarantee XULANE coverage or reimbursement.

Please see full Important Safety Information on pages 20 and 21 and accompanying [Consumer Brief
Summary of Information](#), including **Boxed WARNING**.

References: 1. XULANE Prescribing Information 03/22, Morgantown, WV; Mylan Pharmaceuticals Inc.
2. IQVIA Stakeholder Analytics, MAT November 2021.

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