

Frequently Asked Questions

Get answers to frequently asked questions so you can better direct your future with ENVARSUS XR.



Q What are immunosuppressants?



Your body has a natural defense called the immune system that fights off things like bacteria and viruses to keep you from getting sick.



When you get a kidney transplant, your immune system may think your new kidney is a foreign invader and try to attack it. This is called organ rejection.



Immunosuppressants (im-you-no-soo-pres-ants) are a type of medicine that keep your immune system from attacking or hurting your new kidney.



Like most patients, you may be on more than one immunosuppressant following your kidney transplant. This helps keep your new kidney healthy. Your healthcare team will work with you to find the best medicines to keep your new kidney strong. It is important that you take your medicine as prescribed.

Q What is ENVARSUS XR?

ENVARSUS XR is a once-daily prescription immunosuppressant used with other medicines to help prevent organ rejection in adults who have had a kidney transplant. The active ingredient in ENVARSUS XR is called tacrolimus.

Only ENVARSUS XR extended-release tablets are specially made to deliver smooth and steady levels of tacrolimus over 24 hours with just one daily dose.

ENVARSUS XR has not been studied for safety and efficacy in children under 18 years of age.

Q Do immunosuppressants have side effects?

Yes. Some of the most common side effects are*:

- Diarrhea
- Infection (including urinary tract infection)
- Low red blood cell count (anemia)
- High blood pressure (hypertension)
- Constipation
- Tremors
- Diabetes mellitus
- Peripheral edema (swelling in the hands or feet)
- High blood potassium (hyperkalemia)
- Headache
- Increased blood creatinine
- Nausea
- Vomiting
- Abdominal pain
- Difficulty sleeping

Your healthcare team will work to balance your immune system just enough to protect your kidney, but not so much that you might get an infection or have other side effects.

*The side effects listed are cited from the ENVARSUS XR Medication Guide and resources created by the American Society of Transplantation, American Kidney Fund, and United Network for Organ Sharing. Be sure to review the Medication Guide(s) that came with your prescriptions for important safety information.

Important Safety Information

What is the most important information I should know about ENVARSUS XR?

ENVARSUS XR can cause serious side effects, including:

Increased risk of cancer. People who take ENVARSUS XR have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma).

Increased risk of infection. ENVARSUS XR is a medicine that affects your immune system. ENVARSUS XR can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ENVARSUS XR that can cause death.

Please see Important Safety Information throughout and on pages 5-7. Please see accompanying Medication Guide and full Prescribing Information, including Boxed Warning.

Q Do I have to keep taking immunosuppressants?

Yes. It is very important that you take your immunosuppressive medicines exactly as your healthcare provider has prescribed. Missing even a single dose can increase the chance of your new kidney being rejected.

Only follow your healthcare provider's instructions for taking any immunosuppressant. If you are not sure what to do, ask your healthcare provider.

Q How is ENVARSUS XR different from other immunosuppressants?

ENVARSUS XR is the only once-daily extended-release tablet that helps you have control over your immunosuppression.

If the level of tacrolimus in your body gets too high or too low, it can be harmful to you. ENVARSUS XR has unique technology that works behind the scenes to help keep your immunosuppression at the right level, protecting your kidney from rejection for 24 hours.

Q How do I take ENVARSUS XR?

If you are switching to ENVARSUS XR from a different tacrolimus product, follow your healthcare provider's instructions exactly as they have directed.

- **Take ENVARSUS XR once-daily tablets** with fluid (preferably with water) on an empty stomach, at least 1 hour before a meal or 2 hours after a meal, at the same time each day (preferably in the morning). Decide on a time with your healthcare provider so they will know what time of day to schedule your blood tests.
- **Swallow ENVARSUS XR tablets whole. Do not** chew, divide, crush, or dissolve ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your healthcare provider.
- If you take too much ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.
- You should not eat grapefruit or drink grapefruit juice while taking ENVARSUS XR.
- You should not drink alcohol while taking ENVARSUS XR.
- Tell your healthcare provider if you have any side effects that bother you or that do not go away. Call your healthcare provider for medical advice about side effects.

Important Safety Information (cont)

Who should not take ENVARSUS XR?

Do not take ENVARSUS XR if you are allergic to tacrolimus or any of the ingredients in ENVARSUS XR.

What should I tell my healthcare provider before taking ENVARSUS XR?

Before you take ENVARSUS XR, tell your healthcare provider if you:

- plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.

How do I remember to take ENVARSUS XR?

Some simple ways to help yourself remember to take all your immunosuppressive pills as prescribed include:

- Creating a schedule
- Setting alarm clocks, timers, or digital watches
- Staying aware of how much medicine you have left

What if I miss a dose of ENVARSUS XR?

If you miss your dose of ENVARSUS XR, you should take it as soon as possible, but no longer than 15 hours after missing your dose. If you do not notice the missed dose until more than 15 hours later, you should skip it and take the next dose the following morning at your regularly scheduled time.

Do not take 2 doses at the same time. Also, if you miss your dose of ENVARSUS XR, call your healthcare provider as soon as possible.

What are the possible serious side effects of ENVARSUS XR?

ENVARSUS XR can cause serious side effects, including:

- **Increased risk of cancer.** People who take ENVARSUS XR have an increased risk of getting some kinds of cancer, including skin and lymph gland cancer (lymphoma)
- **Increased risk of infection.** ENVARSUS XR is a medicine that affects your immune system. ENVARSUS XR can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ENVARSUS XR that can cause death
- **Call your healthcare provider right away if you have symptoms of an infection such as:** fever; cough or flu-like symptoms; muscle aches; sweats or chills; warm, red, or painful areas on your skin
- **To report side effects, contact Veloxis Pharmaceuticals, Inc. at 1-844-VELOXIS (835-6947) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch**

Important Safety Information (cont)

- have or have had liver, kidney or heart problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. ENVARSUS XR may harm your unborn baby.
 - If you are able to become pregnant, you should use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider about birth control methods that may be right for you.

What should I share with my healthcare provider?

Your healthcare team wants you to live well following your kidney transplant. The best way for them to help you is by letting them know what's going on in your life and with your health.

Before you take ENVARSUS XR, tell your healthcare provider if you:

- Plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.
- Have or have had liver, kidney, or heart problems.
- Have any other medical conditions.
- Are pregnant or plan to become pregnant. ENVARSUS XR may harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. ENVARSUS XR can pass into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

Also, tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements. ENVARSUS XR may affect the way other medicines work, and other medicines may affect how ENVARSUS XR works.

Where can I learn more?

You can find more information about immunosuppressants, including benefits and side effects, and discover more tips on getting the most out of treatment at the following websites:

National Kidney Foundation

www.kidney.org

United Network for Organ Sharing

www.transplantliving.org

American Kidney Fund

www.kidneyfund.org

Important Safety Information (cont)

- Males who have female partners that are able to become pregnant should also use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider before starting treatment with ENVARSUS XR about birth control methods that may be right for you.
- There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARSUS XR. The purpose of this registry is to collect information about your health and of your baby. To enroll in this voluntary registry, call 1-877-955-6877.

Important Safety Information

What is the most important information I should know about ENVARSUS XR?

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Increased risk of infection. ENVARSUS XR is a medicine that affects your immune system. ENVARSUS XR can lower the ability of your immune system to fight infections. Serious infections can happen in people receiving ENVARSUS XR that can cause death.

Call your healthcare provider right away if you have symptoms of an infection such as:

- fever
- cough or flu-like symptoms
- warm, red, or painful areas on your skin
- sweats or chills
- muscle aches

What is ENVARSUS XR?

ENVARSUS XR is a prescription medicine used with other medicines to help prevent organ rejection in people who have had a kidney transplant.

ENVARSUS XR is an extended-release tablet and is not the same as tacrolimus extended-release capsules, tacrolimus immediate-release capsules or tacrolimus for oral suspension. Your healthcare provider should decide what medicine is right for you.

Who should not take ENVARSUS XR?

Do not take ENVARSUS XR if you are allergic to tacrolimus or any of the ingredients in ENVARSUS XR.

What should I tell my healthcare provider before taking ENVARSUS XR?

Before you take ENVARSUS XR, tell your healthcare provider if you:

- plan to receive any live vaccines. Ask your healthcare provider if you are not sure if your vaccine is a live vaccine.
- have or have had liver, kidney or heart problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. ENVARSUS XR may harm your unborn baby.
 - If you are able to become pregnant, you should use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider about birth control methods that may be right for you.
 - Males who have female partners that are able to become pregnant should also use effective birth control before and during treatment with ENVARSUS XR. Talk to your healthcare provider before starting treatment with ENVARSUS XR about birth control methods that may be right for you.
 - There is a pregnancy registry for females who become pregnant and males who have fathered a pregnancy during treatment with ENVARSUS XR. The purpose of this registry is to collect information about your health and of your baby. To enroll in this voluntary registry, call 1-877-955-6877.
- are breastfeeding or plan to breastfeed. ENVARSUS XR passes into your breast milk. You and your healthcare provider should decide if you will breastfeed while taking ENVARSUS XR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, natural, herbal or nutritional supplements.

ENVARSUS XR may affect the way other medicines work, and other medicines may affect how ENVARSUS XR works.

How should I take ENVARSUS XR?

Take ENVARSUS XR exactly as your healthcare provider tells you to take it.

Important Safety Information (cont)

Your healthcare provider may change your dose of ENVARSUS XR if needed. **Do not** stop taking or change your dose of ENVARSUS XR without talking to your healthcare provider.

Take ENVARSUS XR once daily with fluid (preferably water) on an empty stomach, at least 1 hour before or at least 2 hours after a meal, at the same time each day (preferably in the morning).

Take ENVARSUS XR tablets whole. **Do not** chew, divide, crush, or dissolve ENVARSUS XR tablets before swallowing. If you cannot swallow ENVARSUS XR tablets whole, tell your healthcare provider.

If you miss your dose of ENVARSUS XR, it should be taken as soon as possible, but no longer than 15 hours after missing your dose. If the time after you miss your dose is more than 15 hours, the missed dose should be skipped and the next dose should be taken the following morning at your regularly scheduled time. **Do not** take 2 doses at the same time.

If you take too much ENVARSUS XR, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking ENVARSUS XR?

Live vaccines such as flu vaccine through your nose, measles, mumps, rubella, polio by mouth, BCG (TB vaccine), yellow fever, chicken pox (varicella), or typhoid.

Exposure to sunlight and UV light such as tanning machines. Wear protective clothing and use a sunscreen.

You should not eat grapefruit or drink grapefruit juice while taking ENVARSUS XR.

You should not drink alcohol while taking ENVARSUS XR.

What are the possible side effects of ENVARSUS XR?

ENVARSUS XR may cause serious side effects, including:

See “What is the most important information I should know about ENVARSUS XR?”

Problems from medication errors such as graft rejection and other serious reactions.

People who take ENVARSUS XR have sometimes been given the wrong medicine because some medicines have the same ingredient (tacrolimus) as ENVARSUS XR. **Check your ENVARSUS XR when you get a new prescription to make sure you have received the right medicine.**

- Call your healthcare provider right away if you think you were given the wrong medicine.
- Ask your healthcare provider or pharmacist if you are not sure what ENVARSUS XR should look like.

High blood sugar (diabetes). Your healthcare provider may do certain tests to check for diabetes while you take ENVARSUS XR. Call your healthcare provider right away if you have:

- frequent urination
- confusion
- fruity smell on your breath
- increased thirst or hunger
- drowsiness
- nausea, vomiting, or stomach pain
- blurred vision
- loss of appetite

Kidney problems. Kidney problems are serious and common side effects of ENVARSUS XR. Your healthcare provider may do certain tests to check for kidney function while you take ENVARSUS XR.

Nervous system problems. Nervous system problems are a serious and common side effect of ENVARSUS XR. Call your healthcare provider right away if you get any of these symptoms while taking ENVARSUS XR. These could be signs of serious nervous system problems:

Important Safety Information (cont)

- confusion
- numbness and tingling
- vision changes
- coma
- headache
- muscle tremors
- seizures

High levels of potassium in your blood. Your healthcare provider may do certain tests to check your potassium level while you take ENVARSUS XR.

High blood pressure. Your healthcare provider will monitor your blood pressure while you take ENVARSUS XR.

Changes in the electrical activity of your heart (QT prolongation).

Severe low blood cell count (anemia)

The most common side effects of ENVARSUS XR are, diarrhea, urinary tract infection, low red blood cell count (anemia), high blood pressure, and constipation.

These are not all the possible side effects of ENVARSUS XR. For more information, ask your healthcare provider or pharmacist.

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

How should I store ENVARSUS XR?

Store ENVARSUS XR at room temperature between 68° F to 77° F (20° C to 25° C).

Safely throw away medicine that is out of date or no longer needed.

Keep ENVARSUS XR and all medicines out of reach of children.

General information about the safe and effective use of ENVARSUS XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ENVARSUS XR for a condition for which it was not prescribed. Do not give ENVARSUS XR to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ENVARSUS XR. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about ENVARSUS XR that is written for health professionals. For more information, go to www.ENVARSUSXR.com or call 1-844-Veloxis (1-844-835-6947).

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.

Please see accompanying Medication Guide and full Prescribing Information, including Boxed Warning.

